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July 27, 2004

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APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE.**

APPLICATION NUMBER: 60/477,258

FILING DATE: June 10, 2003

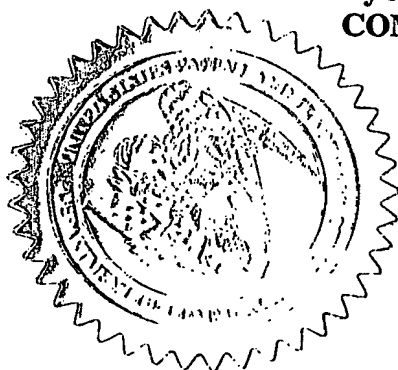
RELATED PCT APPLICATION NUMBER: PCT/US04/18488

REC'D 30 JUL 2004

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06/10/03
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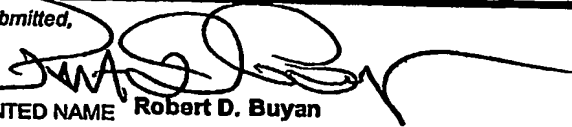
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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)					
Given Name (first and middle (if any))		Family Name or Surname	Residence (City and either State or Foreign Country)		
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<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max) ELECTROSURGICAL DEVICES AND METHODS					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number		33197		<div>Place Customer Number Bar Code Label here</div>	
OR Type Customer Number here					
<input checked="" type="checkbox"/> Firm or Individual Name		Robert D. Buyan			
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Country		U.S.	Telephone	949-450-1750	Fax 949-450-1764
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages		319		<input type="checkbox"/> CD(s), Number	
<input type="checkbox"/> Drawing(s) Number of Sheets				<input checked="" type="checkbox"/> Other (specify)	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76				Appendices A-J; Postcard	
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE AMOUNT (\$)	
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees					
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number		50-0878		\$80.00	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,

SIGNATURE
TYPED or PRINTED NAME Robert D. Buyan
TELEPHONE 949-450-1750

Date 06/10/03
REGISTRATION NO. 32,460
(if appropriate)
Docket Number: NEOME-019N

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C.

Attorney Docket No. NEOME-019N

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Mittelstein, et al.)
Serial No.: To Be Determined)
Filed: Herewith, June 10, 2003)
Title: Electrosurgical Devices and)
Methods)

Transmittal of Provisional Application for Patent
37 CFR 1.53 (b) (2)

Express Mail Mailing Label No. EV261457381US

Mail Stop Provisional Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed, for filing in the United States Patent Office under 37 CFR 1.53 (b)(2), please find the following documents:

1. Provisional Patent Application consisting of 319 (including Appendices A-J) total pages, entitled "Electrosurgical Devices and Methods"
2. A completed Provisional Application Cover Sheet consisting of 1 page;
3. Check No. 3055 in the amount of \$80.00; and
4. A Return Postcard

The inventors of the invention(s) disclosed in this Provisional Patent Application are:

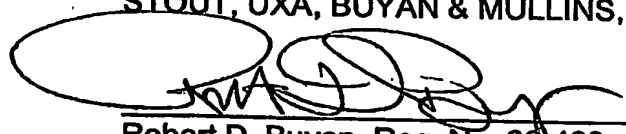
Michael Mittelstein
John T. Sorenson
Soheila Mirhashemi
and
James B. Gerg

The Notice to File Missing Parts (Filing Date Granted) should be mailed to applicant's undersigned counsel at the address shown here below.

Respectfully submitted,

STOUT, UXA, BUYAN & MULLINS, LLP

Date: June 10, 2003


Robert D. Buyan, Reg. No. 32,460

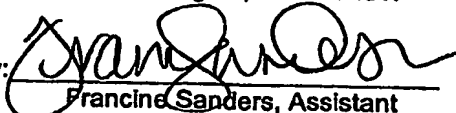
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CERTIFICATE OF MAILING

I hereby certify that this transmittal letter and the accompanying Provisional Patent Application entitled "Electrosurgical Devices and Methods" are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on June 10, 2003 and is addressed to Box Provisional Application, Commissioner for Patents, Washington, D.C. 20231.

Date: June 10, 2003

By:


Francine Sanders, Assistant

**PROVISIONAL APPLICATION FOR
UNITED STATES PATENT**

by

Michael Mittelstein

John T. Sorenson

Soheila Mirhashemi

and

James B. Gerg

assignors to

NeoMedix Corporation

for

ELECTROSURGICAL DEVICES AND METHODS

**Prepared by Robert D. Buyan
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DOCKET NO. NEOME-019N

Express Mail No. EV261457381US

ELECTROSURGICAL DEVICES AND METHODS

THE INVENTION

The invention comprises new electrosurgical devices, their methods of manufacture and related methods of use for cutting tissue in human or veterinary patients as well as modifications, additions and improvements to the the electrosurgical device and methods disclosed in earlier-filed United States Patent Application Serial No. 10/052,473 published as No. 20020111608 and PCT International Application No. PCT/US02/01665 published as No. WO02/056805A2, the entireties of such United States and PCT applications being expressly incorporated herein by reference. Various embodiments and aspects of the present invention are described in detail in Appendices A-J attached hereto, such Appendices A-j being expressly incorporated herein and forming an integral part of this provisional patent application.

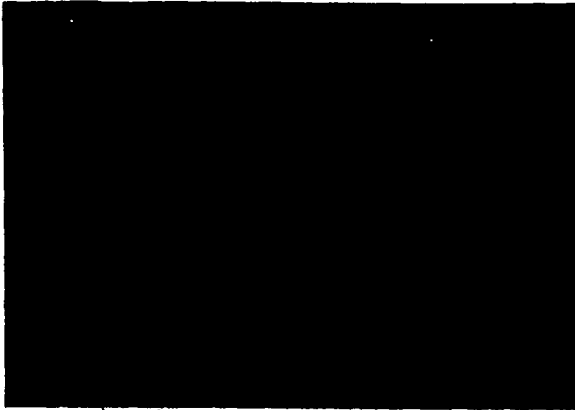
Disclosure Statements in Claim Format:

The invention disclosed herein includes but is certainly not limited to:

1. A device for cutting tissue in a human or veterinary patient, said device comprising:
 - a cutter that's is useable to cut tissue; and
 - a protector positioned relative to the cutter and configured such that, the device may be placed in an operative position wherein the protector is located or interposed between a) tissue that is to be cut and b) tissue that is to be protected and, thereafter, then the electrode is energized, the electrode will cut the tissue that is intended and the protector will prevent the cutter from cutting the tissue that is to be protected.
2. A device according to Claim 1 wherein the cutter comprises at least one tissue cutting electrode, such as a monopolar or bipolar electrode.

3. A device according to Claim 1 or 2 further comprising an infusion lumen through which fluid can be infused into the patient's body and an aspiration lumen through which fluid can be aspirated out of the patient's body.
4. A device according to Claims 1, 2 or 3 wherein the protector is at least partially insulated.
5. A device according to Claim 4 wherein the portion(s) of the protector that are positioned adjacent to or in contact with tissue that is to be protected is/are insulated.
6. A device according to Claim 4 or 5 wherein the protector is at least partially insulated by a polymer coating.
7. A device according to Claim 6 wherein the polymer coating comprises a polyimide coating.
8. A device according to Claims 6 or 7 wherein the polymer coating is applied to at least a portion of the protector by dipping at least a portion of the protector into a liquid polymer solution which subsequently dries and forms a coating on all or a portion of the protector.
9. A device according to any of Claims 1-8 wherein the cutter comprises a bipolar electrode assembly having first and second electrode surfaces.
10. A device according to Claim 9 wherein one of said first and second electrode surfaces is located on the protector.

11. A device according to Claim 10 wherein the protector has at least first and second sides, said protector being configured such that it is positionable with one of its sides adjacent to tissue that is to be cut and another one of its sides adjacent to tissue that is to be protected, and wherein at least one of said electrode surfaces is located on the side of the protector that is positionable adjacent to the tissue that is to be cut.
12. A device according to Claim 11 further comprising insulation on the side of the protector that is positionable adjacent to tissue that is to be protected.
13. A method for cutting a tissue of a human or veterinary patient's body as described in one or more of Appendices A-J hereto.
14. A method according to Claim 13 wherein the method is carried out using a device of any of Claims 1-12.



GONIECTOMY PROJECT

Project Review

Regulatory Plan

Overview

Disease and Invention

Project Review

Regulatory Plan

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GONIECTOMY PROJECT

Project Review

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Overview

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OVERVIEW - GLAUCOMA

Project Review

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Definition of Glaucoma:

Loss of Vision caused by the Destruction of the Optic Nerve

Types of Glaucoma

1. Primary Open Angle Glaucoma
2. Secondary Glaucoma
3. Normal Tension Glaucoma
4. Pigmentary Glaucoma
5. Closed Angle Glaucoma

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OVERVIEW - GLAUCOMA

Project Review

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Primary Open-angle Glaucoma Major Risk Factors:

- High Intraocular Pressure (IOP)
- Age
- Race
- Diabetes
- Systemic Hypertension



Figure provided by the Intl. Glaucoma Association

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GLAUCOMA TREATMENT

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Current Technologies and their Drawbacks

Medication
Filtering Surgery
Goniotomy Surgery

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GLAUCOMA TREATMENT

Discovery and Development

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Medication

Eye drops are typically used to inhibit the high intraocular pressure.

1. Reduces production of intraocular fluid.
and / or
2. Increases drainage of intraocular fluid from the eye.

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GLAUCOMA TREATMENT

Discovery and Development

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Medication***Side Effects:***

Often, the effects of taking the medication are not limited to the eye. Many cause headaches, fatigue, impaired night vision, stinging eyes, reduced cardiac output leading to low blood pressure, or shortness of breath.

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GLAUCOMA TREATMENT

Discovery and Development

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Modern Medication Treatments

Glaucoma treatment often includes a combination of medications due to inadequate effects of a single drug. This in turn may cause a summation of unwanted side effects.

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Discovery and Development

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Filtering Surgery

Drainage holes are created in the sclera to bypass the clogged filtering system in order to lower IOP.

Works as long as it increases the drainage of intraocular fluid from the eye.

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GLAUCOMA TREATMENT

Discovery and Development

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Filtering Surgery***Side Effects:***

Over time the surgically created drainage holes tend to close and the pressure rises due to the patient's healing response. Additional risks include vision changes and risk of infection.

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GLAUCOMA TREATMENT

Discovery and Development

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Laser Trabeculoplasty

A highly concentrated beam of light (laser) is used to create multiple burns in the trabecular meshwork. These burns cause an increased outflow of fluid from the eye.

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GLAUCOMA TREATMENT

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Laser Trabeculoplasty

Side Effects:

IOP decrease is approximately equal to one medication.
Medication is still needed after surgery, in most cases.

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GLAUCOMA TREATMENT

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Intraocular Surgery Goniotomy

*Surgical knives are used to cut an opening or openings
into the Trabecular meshwork to allow fluid to drain
from the eye.*

Surgery works by increasing the drainage of intraocular
fluid from the eye.

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Intraocular Surgery Goniotomy

In children there is a 90% success rate. In adults, the
drainage holes often close due to the patient's healing
response.

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GONIECTOMY PATENT

Project Review

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Patent and Licensing of the Technology

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GONIECTOMY PATENT

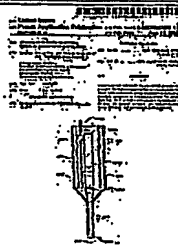
Disease and Invention

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US Patent Published Aug. 15, 2002

Trabeculectomy instrument using
cauterization, laser ablation, sonic,
ultrasonic, or mechanically cutting to
remove a portion of the meshwork. The
instrument may be provided with I & A
and a footplate plate to serve as a guide
along the Schlemm's canal.



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GONIECTOMY PROJECT

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GONIECTOMY DEVICE Development

Disease and Invention

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THE NEW SOLUTION:

The Goniectomy System

Completed by opening and removing a strip of the Trabecular meshwork in a highly atraumatic fashion.



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GONIECTOMY DEVICE Development

Disease and Invention

Regulatory Plan

Theory Behind the Approach

If the Trabecular meshwork is the principle outflow limiting component, then a large opening with a defined edge that maintains the patients Schlemm's canal and collector channels will result in significant, permanent IOP reduction (analogous to the goniotomy in children).

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GONIECTOMY DEVICE Development

Disease and Invention

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Goniectomy: Reduce Eye Pressure

- Sections of the clogged meshwork are removed by mechanical or electrosurgical means.
- These open sections allow fluid flow into the Schlemm's canal and out of the eye through the normal collector channels. This decreases the I.O.P. to low, normal levels.
- This pressure reduction prevents or reduces damage to the optic nerve.

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GONIECTOMY DEVICE

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NeoMedix Development Project

1. History of Handpiece
2. Current Handpiece
3. Integrated Console System
4. Quality Plan

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GONIECTOMY DEVICE

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NeoMedix Development Project

1. History of Handpiece
2. Current Handpiece
3. Integrated Console System
4. Quality Plan

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GONIECTOMY DEVICE Development History

Disease and Invention

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Bladed Goniectomy Design Criteria

1. Based on the bent surgical needle used originally.
2. Sharp pointed footplate to cut the meshwork.
3. Shape of the footplate allows the blade to be guided along the Schlemms canal.



Health Care Solutions

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GONIECTOMY DEVICE Development History

Mechanical Dual Cutting Goniotomy

1. Distal sides of tube facets form the cutting blades.
2. Means to separate a strip of meshwork.



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GONIECTOMY DEVICE Development History

Bladed Goniotomy Design

Conclusions:

1. The footplate was able to guide the blade along the meshwork successfully.
2. The blade was very difficult to manufacture.
3. Blade appeared to tear instead of cut the meshwork.



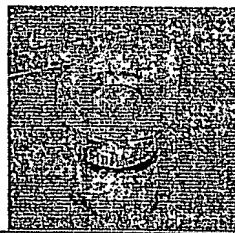
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GONIECTOMY DEVICE Development History

Goniotomy: Simulated Surgery

Specimen holder for excised cornea:

1. Conforming suction cup to retain cornea.
2. Tilt and rotate, lockable holder for convenient access.
3. Means to provide BSS environment for goniotomy.



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GONIECTOMY DEVICE Development History

Goniotomy: Simulated Surgery

Conclusions:

1. Holding power has improved by providing custom conforming cups and suction holes for various specimen shapes.
2. Tilt, rotate, and lock mechanism functioned well.

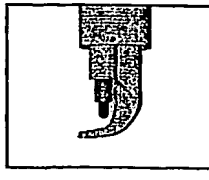


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GONIECTOMY DEVICE Development History

Electrosurgical Goniotomy Design Criteria: First Concept

1. Three-tube design supports irrigation and aspiration as well as the electrosurgical cutting means independently.
2. Footplate provides a guide.
3. Discharge center electrode to footplate.



Goniotomy history and 14.01 photo by 6.8.97

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GONIECTOMY DEVICE Development History

Electrosurgical Goniotomy Design Criteria: Insulating footplate Concept

1. Insulating footplate material provides for thermal and electrical protection of the underlying side of Schlemm's canal.
2. Discharge radial from center electrode to surrounding outer electrode.
3. Mechanical (not electrical) support of the footplate by the center electrode.



Goniotomy history and 14.01 photo by 6.8.97

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GONIECTOMY DEVICE Development History

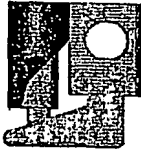
Disease and Invention

Project Review

Regulatory Plan

Electrosurgical Goniectomy Manufacturability Criteria

1. Insertable insulating footplate.
2. Fabrication options include machining, molding, casting.



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GONIECTOMY DEVICE Development History

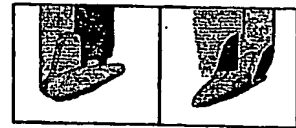
Disease and Invention

Project Review

Regulatory Plan

Electrosurgical Goniectomy Plastic footplate Fabrication Criteria:

1. Micro-lathe utilized to fabricate footplate.
2. Attachment by squeezing and bonding to support tube (Aspiration tube) with or without provided notches.



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GONIECTOMY DEVICE Development History

Disease and Invention

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Electrosurgical Goniectomy Concept: Integration into Handpiece

1. Internal tubing with distal connections to irrigation and aspiration tubes of the needle front end and wiring soldered to the electrodes.
2. Handpiece Assembly.



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GONIECTOMY DEVICE Development History

Disease and Invention

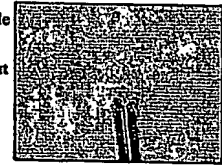
Project Review

Regulatory Plan

Electrosurgical Plastic footplate Goniectomy Design Criteria:

Conclusions:

1. The footplate was able to guide the blade along the meshwork successfully.
2. Plastic footplate was an well-thought out choice to insulate from the electrosurgical arc.
3. Manufacturing the plastic footplate and successfully bonding it to the tip of the handpiece was *extremely* challenging.



Serial No Q20 May 14 92 0.05" 1

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GONIECTOMY DEVICE Development History

Disease and Invention

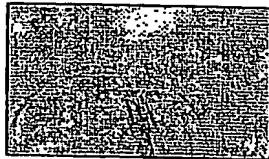
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Axial Discharge Goniectomy: Return to a non-insulated footplate

Conclusions:

1. The footplate was too large and clumsy.
2. The design was too bulky.



Serial No 001 Apr 24 92

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GONIECTOMY DEVICE Development History

Disease and Invention

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Electrosurgical Goniectomy

Conclusions:

1. The footplate was able to guide the blade along the meshwork successfully.
2. Blade was not insulated.
3. Manufacturing the triple tube assembly was challenging.



Serial No 004 May 14 92

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GONIECTOMY DEVICE Development History

Disease and Invention

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Goniectomy

Design Concept: Guillotine Cutter

1. Step down size working end.
2. Addition of a guiding foot to position tissue for nibbling cuts.
3. Horizontal narrow opening positioned very close to the distal end of the device.



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GONIECTOMY DEVICE Development History

Disease and Invention

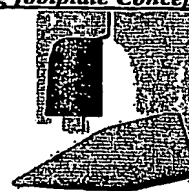
Project Review

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Electrosurgical Goniectomy

Design Criteria: Insulating footplate Concept

1. Machined, cast, or molded insulating shoe with hole to fastened over footplate. Micro-lathed and drilled.
2. Footplate is bent from an extension of the aspiration tube.
3. Still based on triple tube approach.
4. Mechanical (not electrical) support of the footplate by the center electrode.



Goniectomy History may 24 02 a word may 03 04.jpg 0.02"

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GONIECTOMY DEVICE Development History

Disease and Invention

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Electrosurgical Goniectomy

Design Criteria: Insulating footplate Concept

1. Insulating shoe formed from conforming tubing and tapered tip extension formed from glue.
2. Coaxial dual tube approach (no metal jacket around electrode insulation).
3. Holding band formed from the horizontal extensions surrounding electrode insulation like a ring.



Goniectomy History may 24 02 a word may 03 04.jpg 0.02"

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GONIECTOMY DEVICE Development History

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Electrosurgical Polyimide Insulation Goniectomy

Conclusions:

1. The footplate was able to guide the blade along the meshwork successfully.
2. Liquid polyimide coating on the metal footplate insulated the tissue well.
3. Application of the liquid polyimide was relatively easy.



Serial No 012 June 9 02

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GONIECTOMY DEVICE Development History

Disease and Invention

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Clinical Goniectomy Design Criteria:

1. Two coaxial tube design supports irrigation and aspiration.
2. Central insulated but not metal jacketed electrode provides power for the electrosurgical cutting means.
3. Liquid polyimide coating on the metal footplate provides insulation.
4. Means to precisely locate the electrodes with respect to the guiding footplate.

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GONIECTOMY DEVICE Development History

Disease and Invention

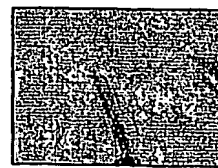
Project Review

Regulatory Plan

Clinical Goniectomy

Conclusions:

1. The footplate was able to guide the blade along the meshwork successfully.
2. Liquid polyimide coating on the metal footplate insulated the tissue well.
3. Application of the liquid polyimide was relatively easy.
4. Design allows for improved and repeatable placement of the electrosurgical electrodes.



Serial No 012 June 19 02

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GONIECTOMY DEVICE Development History

Disease and Invention

Regulatory Plan

Electrosurgical Goniectomy Design Criteria: First Concept

1. Three-tube design supports irrigation and aspiration as well as the electrosurgical cutting means independently.
2. Footplate provides a guide.
3. Discharge center electrode to footplate.

Gonietomy History and 16 81 chart/2/96

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GONIECTOMY DEVICE Development History

Disease and Invention

Regulatory Plan

Electrosurgical Goniectomy Design Criteria: Last Concept

1. Two-tube design supports irrigation and aspiration.
2. Electrosurgical cutting means independent of Footplate.
3. Discharge center electrode to Return electrode.
4. Insulated guiding Footplate.



Gonietomy History and 16 81 chart/2/96

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GONIECTOMY DEVICE

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NeoMedix Development Project

1. History of Handpiece
2. Current Handpiece
3. Integrated Console System
4. Quality Plan

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GONIECTOMY DEVICE CLINICAL DESIGN GOALS

Disease and Invention

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Handpiece Features:

1. Single-use Disposable Hand-held Instrument.
2. Handpiece connects to a fluid control system consisting of I/A and an electrosurgical generator.
3. Tip designed to enter through 20G MVR blade incision.
4. Insulating material covering the tip to isolate the meshwork from thermal and electrical discharge damage.
5. The meshwork guide footplate angled at 90° relative to the handpiece.

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GONIECTOMY DEVICE CLINICAL DESIGN GOALS

Disease and Invention

Regulatory Plan

Handpiece Features: (continued)

- o The handpiece body will consist of a 2 white ABS injection molded parts.
- o Electrode wire made from 316V Stainless Steel.
- o Insulation shoe material made from polyimide.
- o Irrigation / Aspiration tubing pigtails on the handpiece with a separate IA extension tube for easy connection and disposal.
- o Press-on electrosurgical cable connection to the handpiece rear connector.

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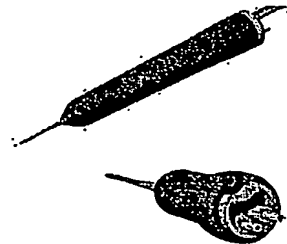
Goniectomy Handpiece Design: Ergonomic Considerations

Disease and Invention

Regulatory Plan

Ergonomic Challenges:

- o Familiar feel in Surgeon's hand.
- o Short (Vitreotomy Style) vs. Long (Pencil Style)
- o Long (Pencil Style) Approach Selected



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Goniectomy Handpiece Design for Manufacturability

Disease and Infection

Regulatory Plan

Manufacturability Obstacles:

- o Clam Shell Approach Considered.
- o Routing Of Tubes And Wires Problematic.
- o Assembly Challenges Guide Design.
- o Desire To Have Greater Manufacturability.



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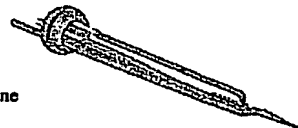
Goniectomy Handpiece Design for Manufacturability

Disease and Infection

Regulatory Plan

Manufacturability Obstacles: (continued)

- o Cap Design simple, but Cable Routing Issues Still not solved.
- o Strain Relief Issues Not Addressed.
- o Non-Rigid Assembly, Prone To Damage.
- o Yield issues after final assembly.



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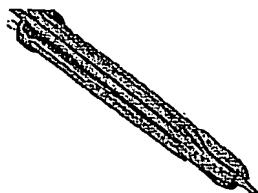
Goniectomy Handpiece Design Solutions

Disease and Infection

Regulatory Plan

Solutions to Manufacturability Obstacles:

- o Redesigned Rear Cap to integrate Inner Holder for all working components.
- o Strain Relief Provided for and Axial Repeatability Enhanced.
- o Tubing Paths Supported.
- o More Robust Sub-Assembly for Testing (Rigid Body).



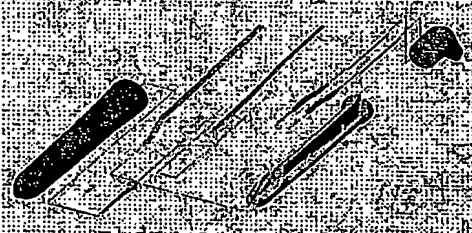
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Goniectomy Handpiece Design : Exploded Assembly

Disease and Infection

Regulatory Plan

o Minimization of components



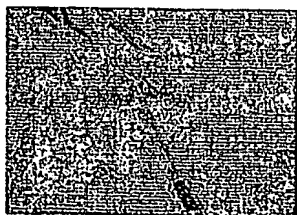
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GONIECTOMY DEVICE In Clinical Environment

Disease and Infection

Regulatory Plan

Goniectomy Device - Clinical Version



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Goniectomy Handpiece Design Goals Achieved

Disease and Infection

Regulatory Plan

Design Goals Reached!

- o Push on BI-Polar Connector fits nearly flush to Handpiece.
- o I/A Tubing are adjacent to the Connector without interference.
- o Surgeon has an ergonomic device to optimize the outcome for the patient
- o Result: Clean, Modular Handpiece Assembly.



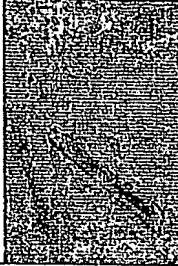
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Goniectomy Handpiece Design : Physical Prototype

Diocese and Invention Project Review Regulatory Plan

Handpiece Summary:

- o Met Design Challenges
- o Overcame Issues of Manufacturability.
- o Integrated Surgeon's Feedback.



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GONIECTOMY DEVICE

Diocese and Invention Project Review Regulatory Plan

NeoMedix Development Project

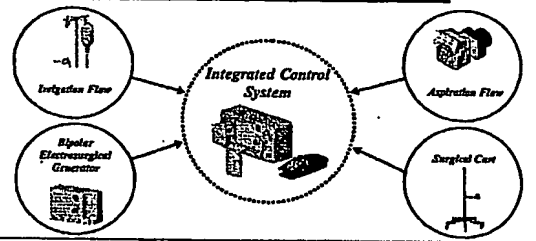
1. History of Handpiece
2. Current Handpiece
- 3. Integrated Console System**
4. Quality Plan

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GLAUCOMA DEVICE

Diocese and Invention Project Review Regulatory Plan

Console Integration Elements



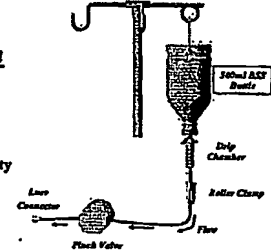
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GLAUCOMA DEVICE

Diocese and Invention Project Review Regulatory Plan

Console Integration: Irrigation Sub-System

- Gravity fed Irrigation of standard 500ml BSS bottle
- Adjustable bottle pole height
- Normally open pinch valve for safety
- Disconnect fitting allows for handpiece exchange



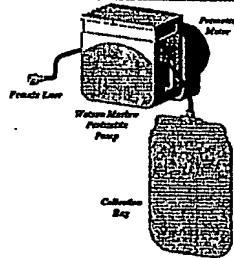
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GLAUCOMA DEVICE

Diocese and Invention Project Review Regulatory Plan

Console Integration: Aspiration Sub-System

- Adjustable rate, flow-based peristaltic pump technology
- Easy tube loading/unloading
- 500 ml collection bag
- No aspiration vacuum level reading or control



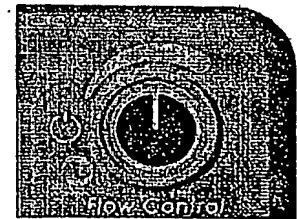
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GLAUCOMA DEVICE

Diocese and Invention Project Review Regulatory Plan

Console Integration: 3-Mode, Selector Control

- 4 Flow Settings:
 - 2 cc/min
 - 4 cc/min
 - 6 cc/min
 - 8 cc/min
- Standby
- Purge

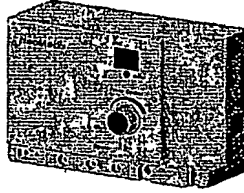


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GLAUCOMA DEVICE

Console Integration Elements: Electrosurgical Sub-System

- Full regulatory approval of Aaron 800EU
- Bipolar and monopolar capable
- Adjustable bipolar power levels from 0.1 to 30W
- Remote foot pedal control
- OEM private label customization available

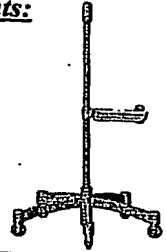


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GLAUCOMA DEVICE

Console Integration Elements: Surgical Cart

- Rolling surgical cart stands available thru GCX and Aaron Medical
- Adjustable irrigation bottle height mechanism
- Surgical tray for temporary holding of handpiece and tray packs
- Accessory storage basket for foot pedal, cabling, manuals, etc.



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GLAUCOMA DEVICE

Console Integration: Design History

- Original stacked configuration of I/A enclosure under Aaron 800EU
- Minimal form factor design intent
- Advantages: Small form factor and standalone I/A capable unit
- Disadvantages: Exposed cabling for foot pedal bypass, exposed monopolar and return plate jacks, difficult to match styling of Aaron 800EU



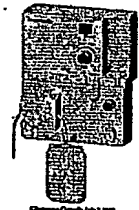
Chassis: Glauco June 22 2002

NeoMedix

GLAUCOMA DEVICE

Console Integration: Design History

- Intended to match the form factor and styling of Aaron 800EU
- Provided plastic extensions to cover unused jack locations of Aaron 800EU
- Advantages: Prevent misconnection of handpiece to incorrect jacks
- Disadvantages: Molding complexity, cleaning issues and mechanical instability resulting from gap between units, difficult to color/text match



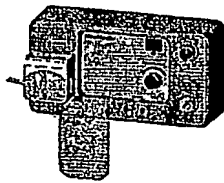
Chassis: Glauco July 2 2002

NeoMedix

GLAUCOMA DEVICE

Console Integration: Design History

- Integrates Aaron 800EU as an enclosed, internal component
- Adds stylized features and curvature
- Advantages: Eliminates 2-part styling mismatch, leaves only usable jacks exposed, mechanically sturdy
- Disadvantages: Requires larger enclosure fabrication and transfer of covered label content on Aaron 800EU



Chassis: Glauco July 2 2002

NeoMedix

GLAUCOMA DEVICE

Applicable Regulatory Standards

- FDA 510K (Class 2)
- UL/cUL 2601
- IEC601
 - IEC60601 [Medical Device Directive]
 - IEC60417-1 [Graphical Symbols Standard]

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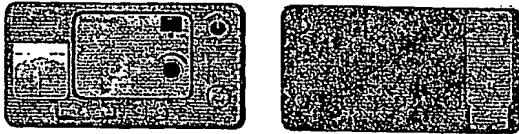
GLAUCOMA DEVICE

Disease and Invention

Project Review

Regulatory Plan

CONSOLE PICTURES



NeoMedix

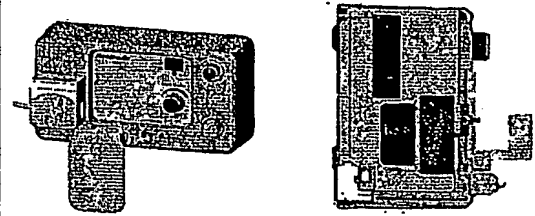
GLAUCOMA DEVICE

Disease and Invention

Project Review

Regulatory Plan

CONSOLE PICTURES II



NeoMedix

GLAUCOMA DEVICE Integrated System

Disease and Invention

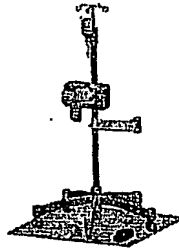
Project Review

Regulatory Plan

•Console

- Fluidics Module
- RF Module

- Stand with tray, irrigation bottle holder
- Irrigation bottle, bottle spike, tubing set
- Foot pedal
- Electrosurgical Cable
- Handpiece



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GLAUCOMA CONSOLE

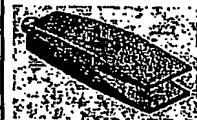
Disease and Invention

Project Review

Regulatory Plan

Footpedal Control - 3-state control system

Footpedal	Function
Region 0	All OFF
Region 1	Irrigation ON
Region 2	Add Aspiration ON
Region 3	Add Electrosurgical ON



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Production

Disease and Invention

Project Review

Regulatory Plan

Design & Productions Capabilities

Disease and Invention

Project Review

Regulatory Plan

- o Stereo lithography rapid prototyping
- o CNC Machining
- o Extensive Manufacturing and Inspection Equipment



NeoMedix

Manufacturing for Productions

- o Class 10,000 Controlled Environment
- o FDA Registered Facility
- o Extensive Manufacturing and Inspection Equipment



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GONIECTOMY DEVICE

NeoMedix Development Project

1. History of Handpiece
2. Current Handpiece
3. Integrated Console System
4. Quality Plan

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Glaucoma Quality Plan

NeoMedix Development Project

Production Development Phases:

1. Prototype
2. Clinical
3. Pre-Production
4. Production

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Glaucoma Quality Plan

NeoMedix Development Project

Prototype Phase:

- | | |
|---------------------------------------|---|
| 1. User Requirement Specification | 8. Clinical Investigation (If applicable) |
| 2. Product Specification (Functional) | 9. Draft of Labeling |
| 3. Initial FMEA (EN 1441) | 10. Documentation |
| 4. In Vitro Testing | 11. Design review |
| 5. In Vivo Testing | 12. Process Requirement Defined |
| 6. Biocompatibility Method | 13. Special and Key Processes Identified |
| 7. Sterilization Method | 14. Receiving Inspection |

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Glaucoma Quality Plan

NeoMedix Development Project

Clinical Phase:

- | | |
|------------------------------------|-----------------------------------|
| 1. Validation Test Report | 8. Labeling Completed |
| 2. Completed FMEA | 9. Environmental Controls |
| 3. Equipment Validation | 10. Vendor Qualification |
| 4. Process Control in Place | 11. Manufacturing Instruction |
| 5. Biocompatibility Completed | 12. Process Instruction |
| 6. Sterilization Validation Report | 13. Drawings Release |
| 7. Design Review | 14. Bill of Materials Release |
| | 15. In-process, Final Instruction |
| | 16. Device History Record |

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Glaucoma Quality Plan

NeoMedix Development Project

Pre-Production:

1. FDA Clearance
2. Foreign Approvals (CE)
3. Document Release
4. Design Review
5. Device Master Record
6. Corrective Action System

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Glaucoma Quality Plan

Disease and Invention

Project Review

NeoMedix Development Project

Production:

1. Failure Analysis Performed
2. Corrective Action System
3. Internal Audits Performed
4. Documents Release
5. Design Review

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GONIECTOMY DEVICE

Disease and Invention

Regulatory Plan

NeoMedix Development Project

1. History of Handpiece
2. Current Handpiece
3. Integrated Console System
4. Quality Plan

Done

NeoMedix

GONIECTOMY PROJECT

Disease and Invention

Project Review

Overview

Disease and Invention

Project Review

Regulatory Plan

NeoMedix

Manufacturing Instructions

MI 400018

Title: MI - Irrigation Sheath Subassy

Rev: A

Prepared By: James Gerg

Release Level: Clinical

ECN No:

Release Approved By:

Date:

412-03

J. Saenz

04/24/03

1.0 PURPOSE

Details the steps required to assemble the Irrigation Sheath Subassy, for personnel experienced in assembling disposable medical devices.

2.0 TOOLS AND SUPPLIES

- Lesco SuperSpot Max UV Cure System or equivalent
- Lesco single, dual, or triple light guides or equivalent
- UV protective eyewear
- UV protective gloves, UVPS- NT Surgical Type, non-powdered
- Nikon Microscope P/N SM2645 or equivalent
- Dynalite 150 (150Watt) light source or equivalent
- 27G x 1/2" SS dispensing tips (EFD P/N 5127-B or equivalent)
- Tip Alignment Fixture [NeoMedix P/N 300023]

3.0 MATERIALS

All materials are listed in the assembly drawing NeoMedix P/N 500018.

Additional referenced documents: N/A

NEOMEDIX Corporation

Title: MI - Irrigation Sheath Subassy

MI 400018

Rev. A

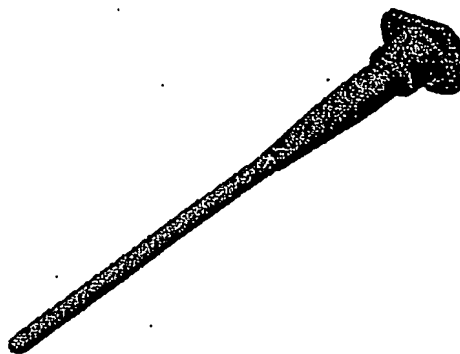
4.0 PROCEDURE

FIGURE 1. Finished Subassembly

4.1 UV CURE SYSTEM AND LOCTITE 4304 ADHESIVE BOTTLE SETUP

- 4.1.1 Turn ON the Lesco SuperSpot UV Cure System and allow a 10-minute warm-up period.
- 4.1.2 Adjust the power setting to minimum. Set the cure cycle time to 6.0 seconds.
- 4.1.3 Insert a suitable light guide into the Lesco SuperSpot UV Cure System.
- 4.1.4 Press-fit a 27Ga x 1/2" dispensing tip firmly onto the male luer taper fitting of the Loctite 4304 Adhesive [NeoMedix P/N 200068] bottle.
- 4.1.5 Wear UV protective gloves during all assembly steps and UV protective eyewear during all UV adhesive cure cycles.

4.2 BONDING THE IRRIGATION SHEATH SUBASSY

- 4.2.1 Visually inspect the 20G Irrigation Sheath Tube [P/N 100083] (see Figure 2) under the microscope for burrs in the cross-drilled side holes or obstructions in the inner diameter. (Do not use parts with burrs or obstructions. Parts may be deburred and/or recleaned for minor defects.)

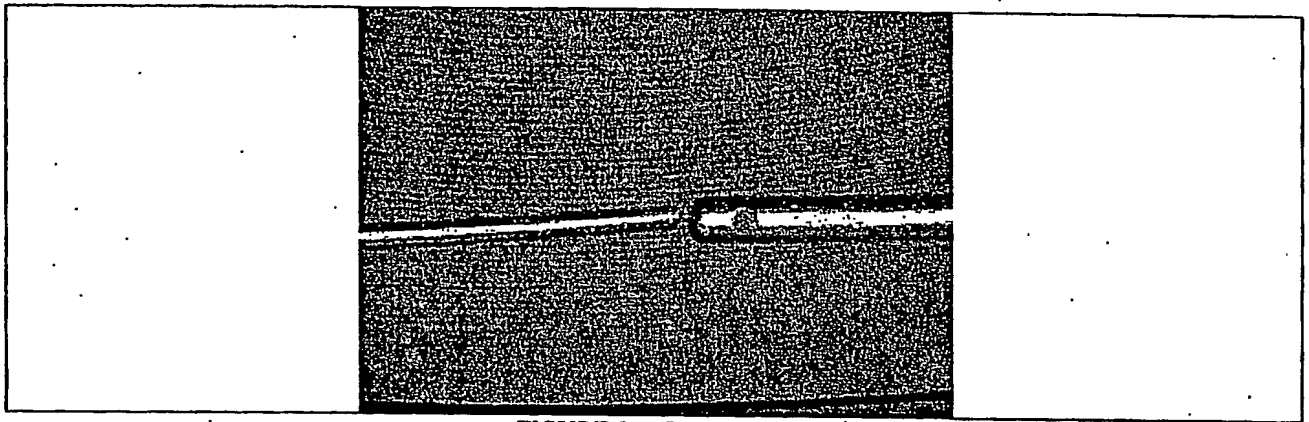


FIGURE 2. Inspection of Cross-drilled Holes for Burrs)

- 4.2.2 Visually inspect the Irrigation Sheath Hub [P/N 100082] under the microscope for burrs on flat edge of D-flange feature or inside counterbores. (Do not use parts with burrs. Parts may be deburred and recleaned for minor defects.)
- 4.2.3 Visually inspect the Irrigation Sheath Hub under the microscope for machining defects to the flat edge of D-flange feature including radiusing of the corner edges. Split any parts with non-flat D-features to a separate Work Order and label packaging as requiring extra attention to assure assembly rotational alignment in subsequent assembly steps.
- 4.2.4 Insert the square-cut end of the 20G Irrigation Sheath Tube into the inner bore of the small, tapered end of the Irrigation Sheath Hub as shown in Figure 3. (NOTE: Initial insertion should be approximately 0.10").

NEOMEDIX Corporation

Title: MI - Irrigation Sheath Subassy

MI 400018

Rev. A

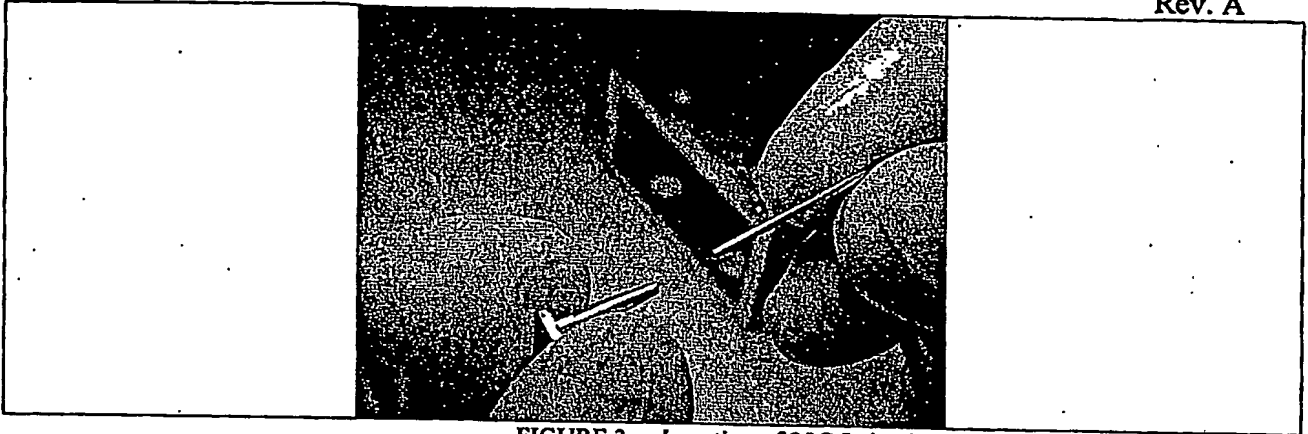


FIGURE 3. Insertion of 20G Irrigation Sheath Tube Into Irrigation Sheath Hub

- 4.2.5 Retract the spring-loaded Seating Pin of the Tip Alignment Fixture [P/N 300023] (see Figure 4a) until it is held in an open position by the fixture's ball detent feature as shown in Figure 4b.

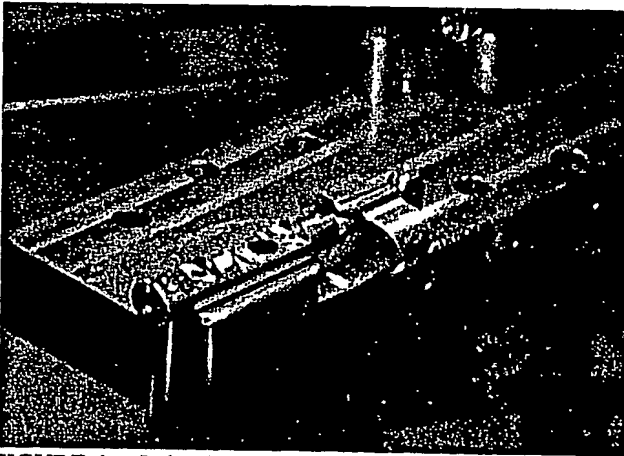


FIGURE 4a. Irrigation Sheath Fixture

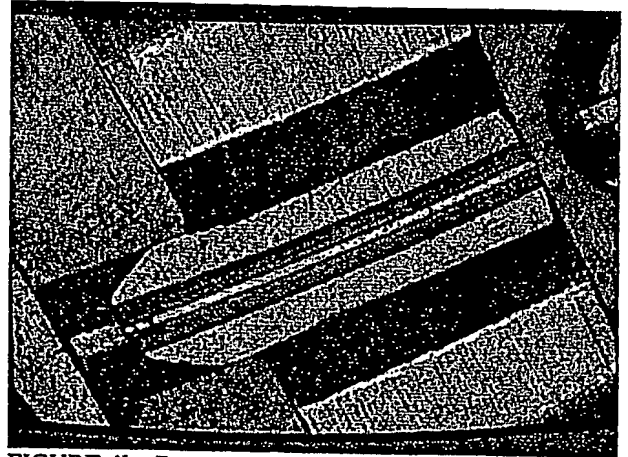


FIGURE 4b. Retracted Fixture Seating Pin

- 4.2.6 Place the the loosely inserted subassembly into the fixture by first placing the cross-drilled irrigation outflow holes at the distal tip of the 20G Irrigation Sheath Tube onto the fixture's Rotational Alignment Pin as shown in Figures 5a and 5b.

NEOMEDIX Corporation

Title: MI - Irrigation Sheath Subassy

MI 400018

Rev. A

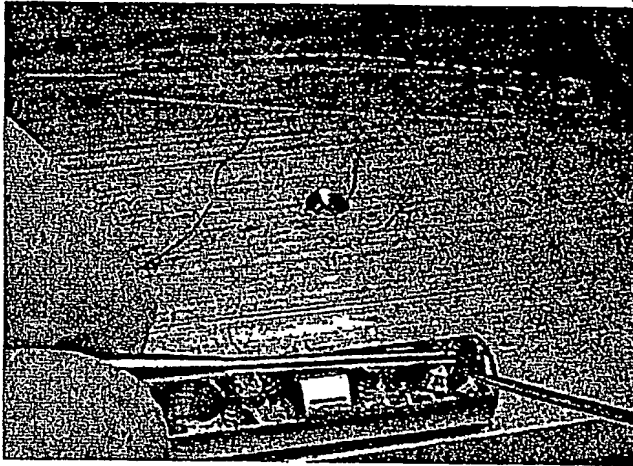


FIGURE 5a. Placing Loose Subassembly Into Fixture

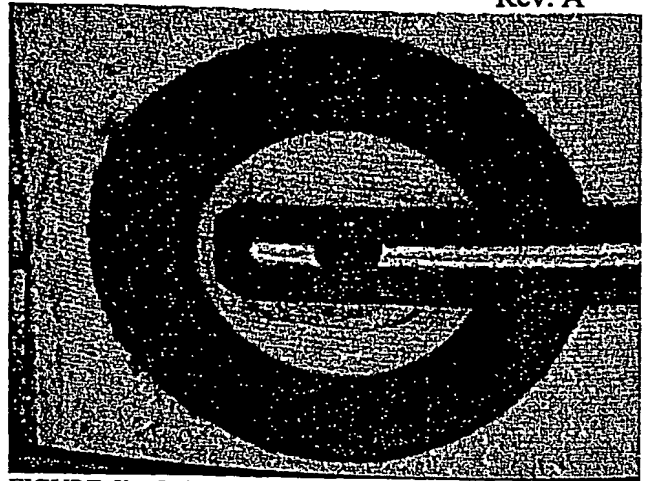


FIGURE 5b. Irrigation Hole Placement Onto Alignment Pin

- 4.2.7 Push the Irrigation Sheath Hub's D-shaped flange against the fixture stop as shown in Figure 6 and retract the Seating Pin into a clamped position.

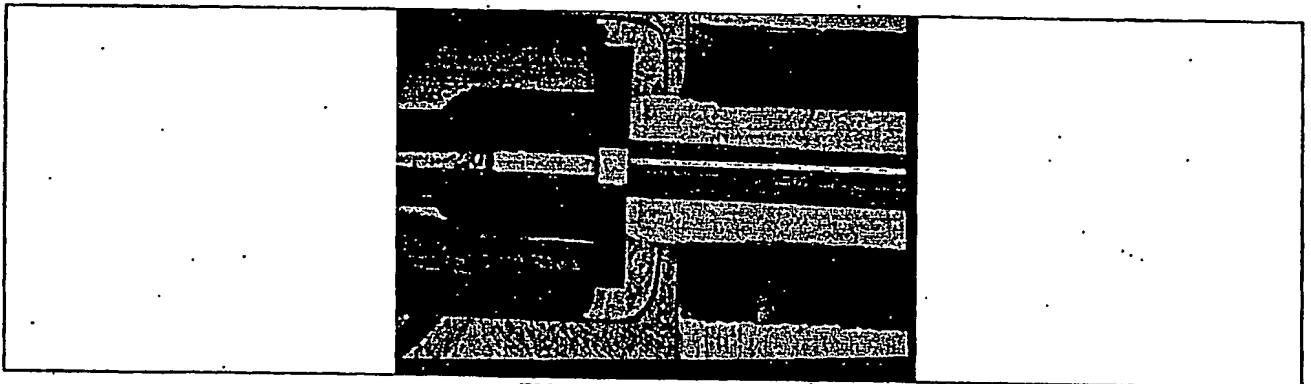


FIGURE 6. Clamp Positioning of Irrigation Sheath Hub in Fixture

- 4.2.8 Apply 1 small drop of Loctite 4304 adhesive [P/N 200068] from a 27G SS dispensing tip to the location where the 20G Irrigation Sheath Tube exits the Irrigation Sheath Hub as shown in Figure 7. (Dispensing too much adhesive and/or waiting too long before the initial UV curing in Step 4.2.9 is likely to cause adhesive to flow into and obstruct the inner diameter of the tube.)

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Title: MI - Irrigation Sheath Subassy

MI 400018

Rev. A

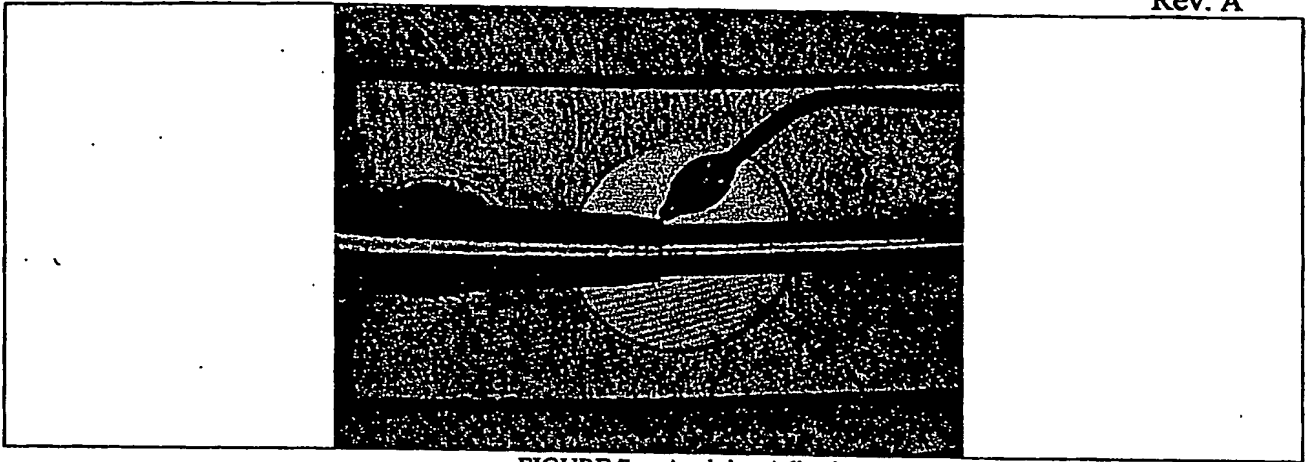


FIGURE 7. Applying Adhesive to Irrigation Sheath Bond Site

- 4.2.9 Use the dispensing tip to evenly distribute the dispensed adhesive drop around the circumference of the bond joint location paying special attention to the non-viewable side of the joint closest to the base of the fixture as shown in Figure 8.

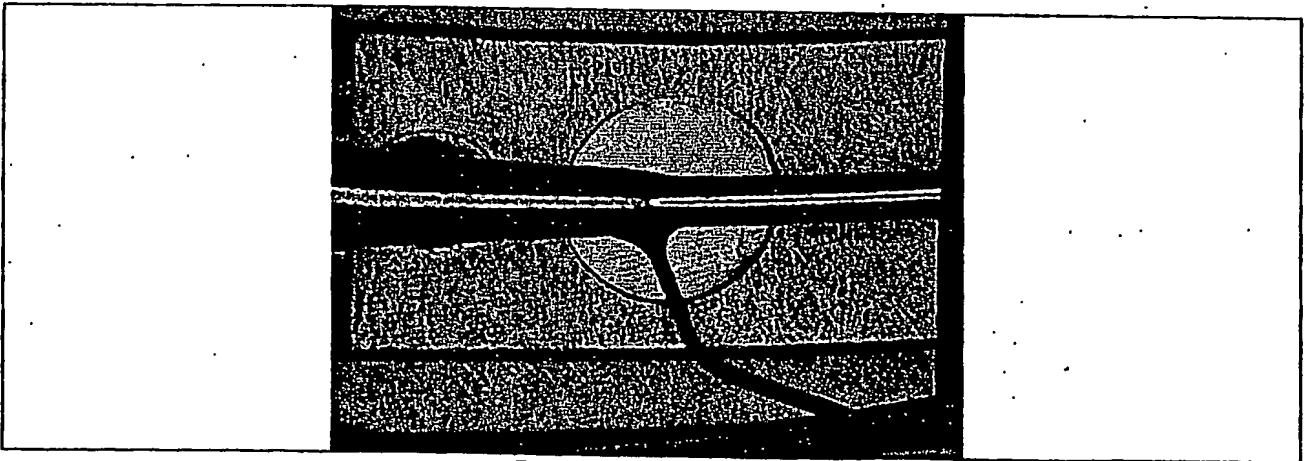


FIGURE 8. Distributing Adhesive Drop Around Tube Circumference

- 4.2.10 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the tip of a single light guide positioned approximately 3" from the bond site. (Direct UV light coaxially through the open D-flange end of the subassembly for at least 4 seconds to ensure that the adhesive is fully cured internally and will not later flow and obstruct the tube inner bore.)

NEOMEDIX Corporation

Title: MI - Irrigation Sheath Subassy

MI 400018

Rev. A

- 4.2.11 Apply 2 additional small drops of Loctite 4304 adhesive [P/N 200068] from a 27G SS dispensing tip to the location where the 20G Irrigation Sheath Tube exits the Irrigation Sheath Hub and completely cover over the existing cured adhesive bond.
- 4.2.12 Use the dispensing tip to evenly distribute the dispensed adhesive drops around the circumference of the bond joint location paying special attention to the non-viewable side of the joint closest to the base of the fixture.
- 4.2.13 Cure adhesive with two 6-second minimum cycles of the Lesco SuperSpot Max UV Cure System set to minimum power with the tip of a single light guide positioned approximately 3" from the bond site. (It is not necessary to direct any more UV light into the inside of the subassembly as was done previously in Step 4.2.10.)
- 4.2.14 Retract the spring-loaded Seating Pin and remove the subassembly from the fixture.
- 4.2.15 Rotate the assembly over and view towards the D-shaped flat of the Irrigation Sheath Hub's flange (see Figure 9) for any circumferential gaps in the adhesive. If any gaps are present, reapply Loctite 4304 adhesive to the gap areas, evenly distribute the adhesive around the circumference of the bond joint, and cure the UV adhesive per MI Steps 4.2.11 through 4.2.13.

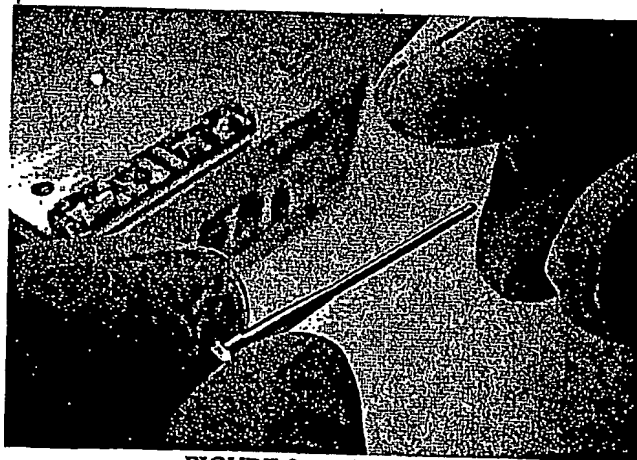


FIGURE 9. Checking for Circumferential Gaps in Adhesive Bond

NEOMEDIX Corporation

Title: MI - Irrigation Sheath Subassy

MI 400018

Rev. A

4.3 INSPECTING SUBASSEMBLIES AND COMPLETING THE WORK ORDER

- 4.3.1 Verify both the rotational and axial dimensional specifications on the assembly drawing. ("REJECT" any assemblies that do not conform to dimensional specifications.)
- 4.3.2 Verify that there is no adhesive outside the limits specified on the assembly drawing. ("REJECT" any assemblies that have cured adhesive outside of specified bond regions.)
- 4.3.3 Visually inspect that the axis of the 20G Irrigation Sheath Tube is straight relative to the axis of the Irrigation Sheath Hub.
- 4.3.4 Pass a 0.0208" gage pin completely through the inner bore of the assembly. ("REJECT" any assemblies that do not conform to this specification likely caused by adhesive occluding the inner bore.)
- 4.3.5 Place all "ACCEPTED" assemblies in polybags labeled with NeoMedix P/N, WO#, quantity, and date into the Clean Room pass through.
- 4.3.6 Place all "REJECTED" assemblies in clean poly bags labeled with "REJECTED", NeoMedix P/N, WO#, quantity, and date. ("Rejected" assemblies should be placed in a designated QC Quarantine area for later review.)
- 4.3.7 Mark all packages of unused and unopened parts as "Return to Inventory".
- 4.3.8 Mark all packages of parts not used due to defects with "Defective Parts" along with the WO#, quantity, and any pertinent description. ("Defective Parts" should either be discarded or reviewed if possible by Mfg/QC Engineering.)
- 4.3.9 Clean all "ACCEPTED" assemblies for 3 minutes maximum in an ultrasonic IPA bath and blow dry immediately with Nitrogen in "Flow Bench."
- 4.3.10 Verify the count of "ACCEPTED" assemblies after cleaning and package in clean poly bags handling parts at all times with clean, powder-free gloves.
- 4.3.11 Verify the total number of "ACCEPTED" and "REJECTED" parts, record the data on the Work Order, return all documents to the Completed Work Order File, and log all "ACCEPTED" and cleaned materials into inventory.

NEOMEDIX
Corporation

27452 Calle Arroyo
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TEL: (949) 248-7029
FAX: (949) 248-7119

Manufacturing Instructions

MI 400020

Title: MI - Aspiration Tube with Return Electrode – Formed and Insulated

Rev. A

Prepared By: James Gerg

Release Level: Clinical

ECN No:

Release Approved By:

Date:

413-03

J. Soenen

04/24/03

1.0 PURPOSE

Details the steps required to convert the Aspiration Tube with Return Electrode – Electropolished and Plated [P/N 100061-02] into the Aspiration Tube with Return Electrode – Formed and Insulated [P/N 100061-06], for personnel experienced in assembling disposable medical devices. The steps include bending the metal tabs of the Aspiration Tube with Return Electrode, applying a conformal liquid Polyimide coating to selective regions, curing the Polyimide, and reforming the metal tabs.

2.0 TOOLS AND SUPPLIES

- Nikon Microscope P/N SM2645 or equivalent
- Dynalite 150 (150Watt) light source or equivalent
- 2" long lengths of 0.006" diameter 304V SS wire [NeoMedix P/N 200083-03 or equivalent] (for applying Liquid Polyimide)
- Aspiration Tube Forming Fixture [NeoMedix P/N 300018]
- Aspiration Tube Holder [NeoMedix P/N 300024]
- 3cc polypropylene transfer syringe
- Clean anti-static polyethylene bag
- UV protective gloves, UVPS- NT Surgical Type, non-powdered
- Extra fine pointed tweezers
- ≥1 cubic foot, ≥300°F regulated vacuum oven (NAPCO Model 5831 or equivalent)

3.0 MATERIALS

All materials are listed in the specification drawing for NeoMedix P/N 100061.

Additional referenced documents: N/A

Confidential

CONTROL DOCUMENT

Page 1 of 11

NEOMEDIX Corporation

Title: MI - Aspiration Tube with Return Electrode – Formed and Insulated MI 400020

Rev. A

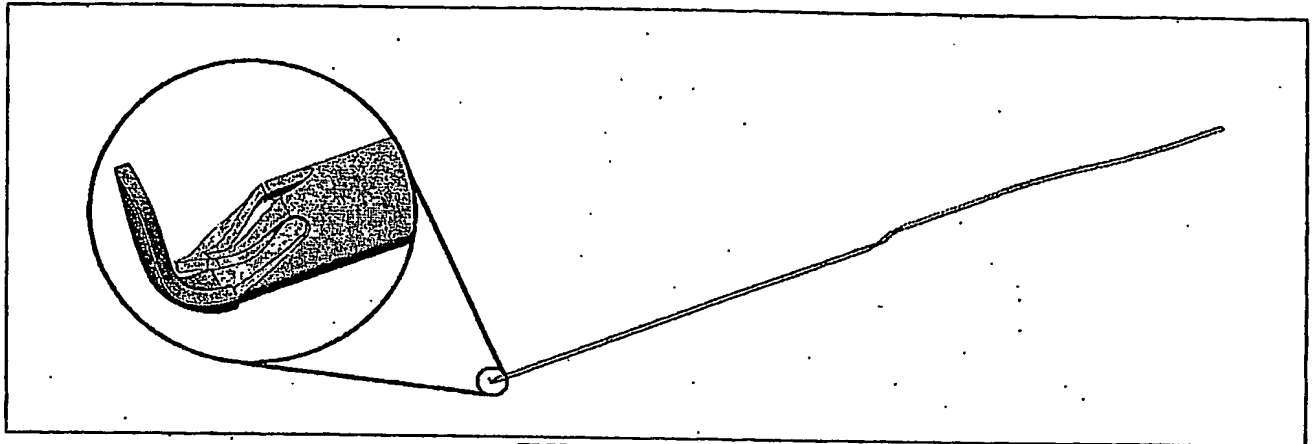


FIGURE 1. Completed 100061-06 Configuration

4.0 PROCEDURE

4.1 FLARING OUT "RETURN TAB"

4.1.1 Wear gloves for all assembly steps.

4.1.2 Place Aspiration Tube with Return Electrode – Electropolished and Plated [P/N 100061-02] in the v-groove of the Aspiration Tube Forming Fixture [P/N 300024] that is not aligned with the fixture's vertical forming pin and position the sharp pointed distal tip approximately 0.060" from the edge of the fixture. (The Aspiration Tube should be rotationally positioned as shown in Figure 2.)

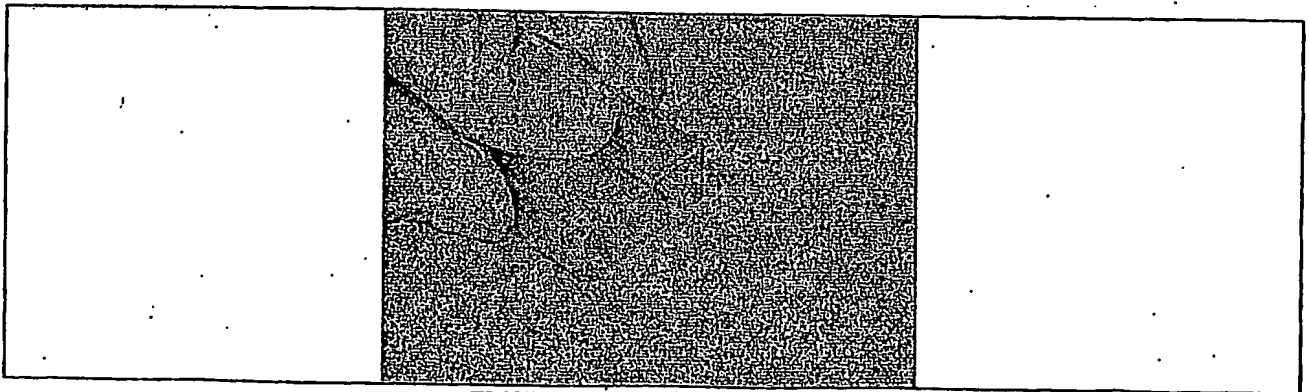


FIGURE 2. Positioning Aspiration Tube in Fixture V-groove

NEOMEDIX Corporation

Title: MI - Aspiration Tube with Return Electrode - Formed and Insulated MI 400020

Rev. A

- 4.1.3 Grasp the "Return Tab" (see Figure 3) with sharp pointed tweezers in the region distal to the spade shaped inner cutout.

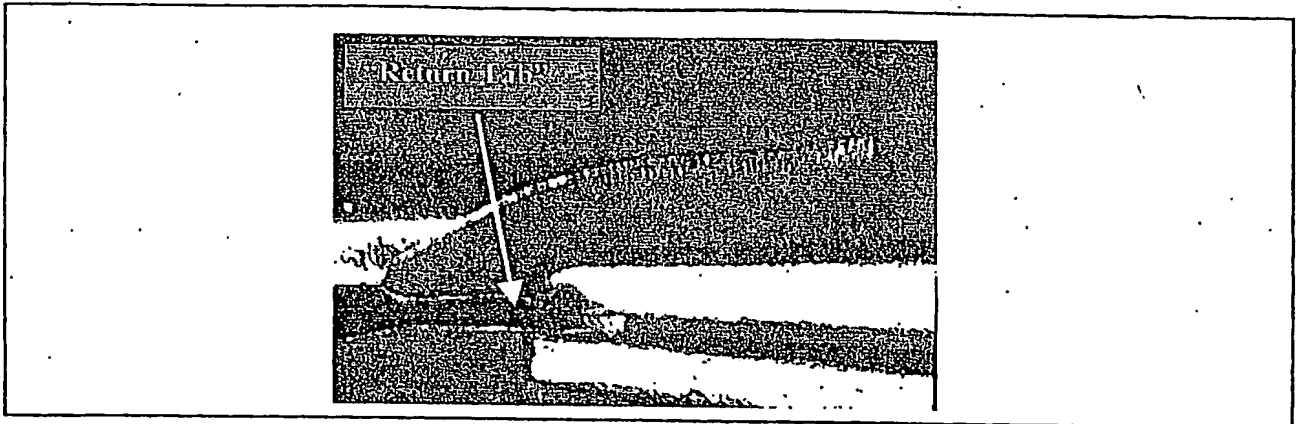


FIGURE 3. Gripping Position of Tweezers on "Return Tab"

- 4.1.4 Flatten the "Return Tab" with squeezing pressure on the tweezers and bend the tab at a slight angle radially outwards as shown in Figure 4.

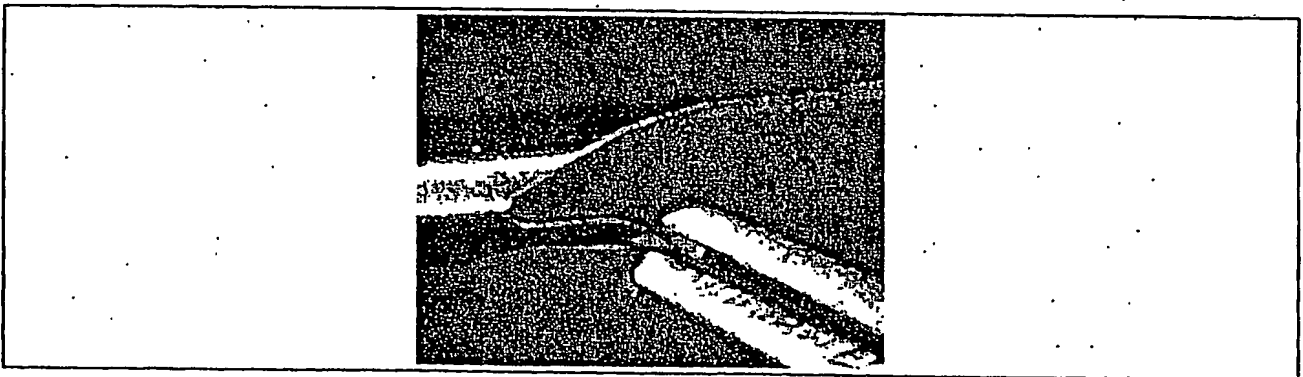


FIGURE 4. Flattening and Bending "Return Tab" Distal Tip

- 4.1.5 Insert the tweezers into the inner diameter of the Aspiration Tube as shown in Figure 5a and bend the "Return Tab" radially outwards to the position shown in Figure 5b using the tweezers' closed tip contact point with the ID of the tube as a pivot.

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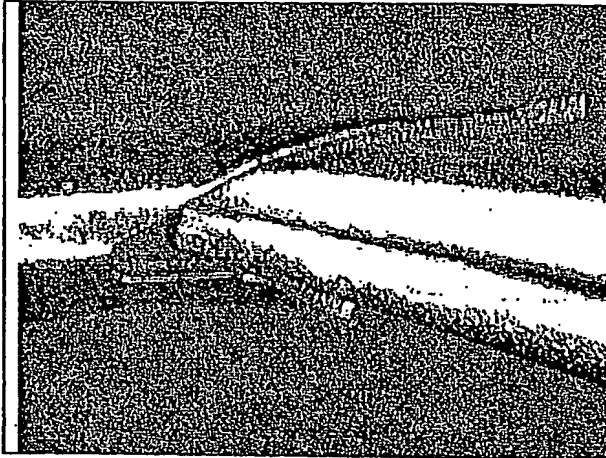


FIGURE 5a. Tweezers Tip Pivot Location

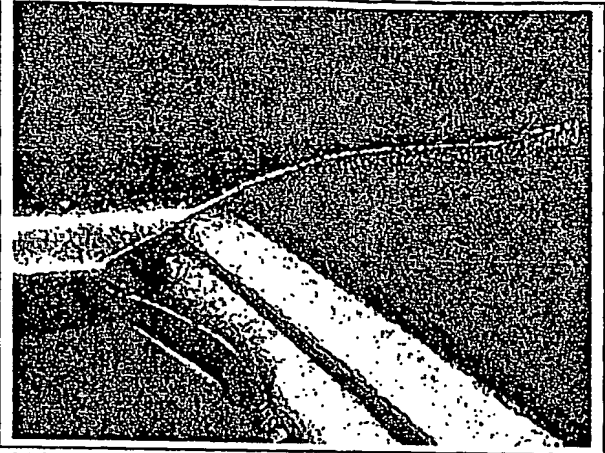


FIGURE 5b. Final "Return Tab" Bending Position

4.2 FORM THE "FOOT"

- 4.2.1 Place the Aspiration Tube in the v-groove of the Aspiration Tube Forming Fixture with the "Return Tab" and the longer "Shoe Tab" oriented as shown in Figure 6 with respect to the fixture's vertical "Forming Wire".

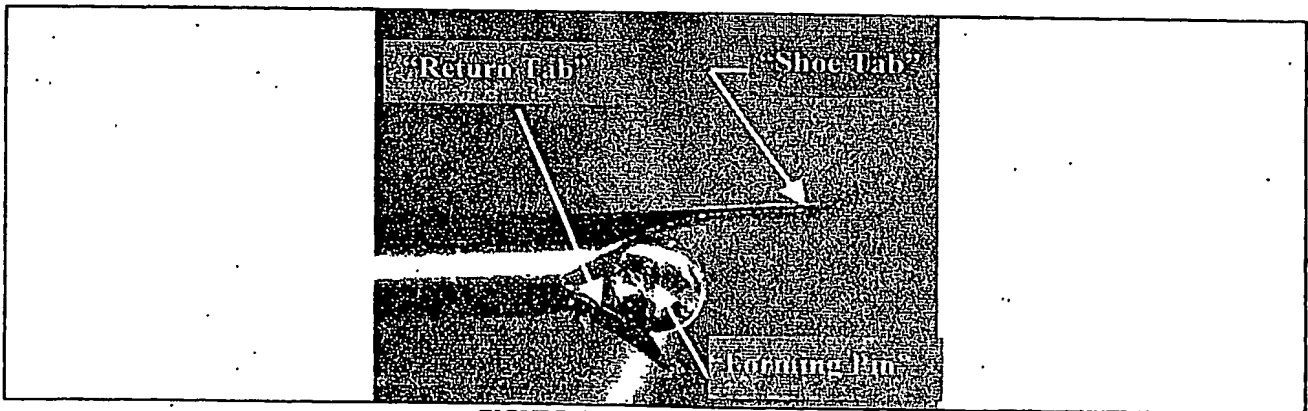


FIGURE 6. Positioning of Aspiration Tube Against Fixture Forming Wire

- 4.2.2 Place the smooth handle end of the tweezers in contact with the outside of the Aspiration Tube as shown in Figure 7.

NEOMEDIX Corporation

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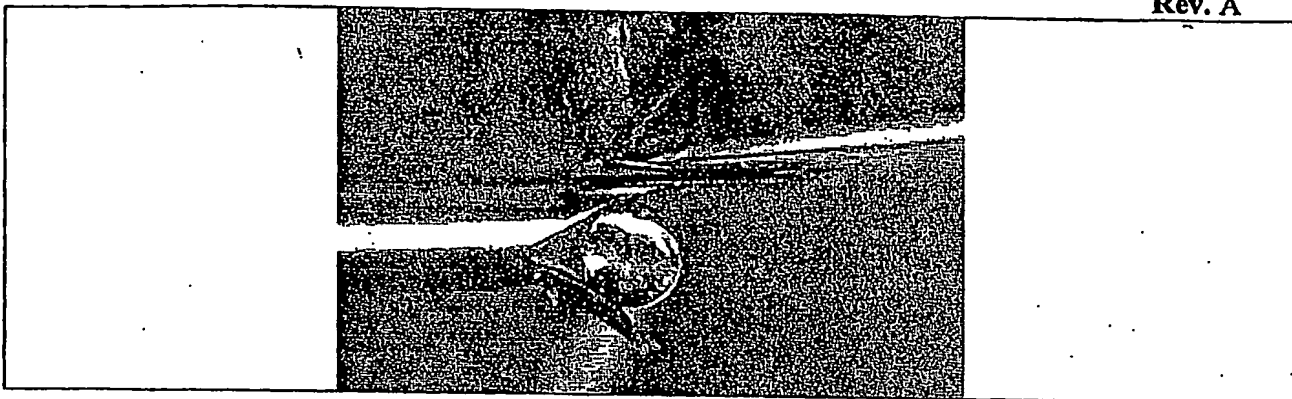


FIGURE 7. Starting Position for Tweezers

- 4.2.3 While maintaining the axially positioning of the Aspiration Tube with the vertical fixture pin in simultaneous contact with both the "Return Tab" and the "Shoe Tab", rotate the tweezers parallel to the base of the fixture making sure to keep constant radial pressure on the "Shoe Tab" with respect to the vertical "Forming Pin". (See Figures 8a and 8b.)

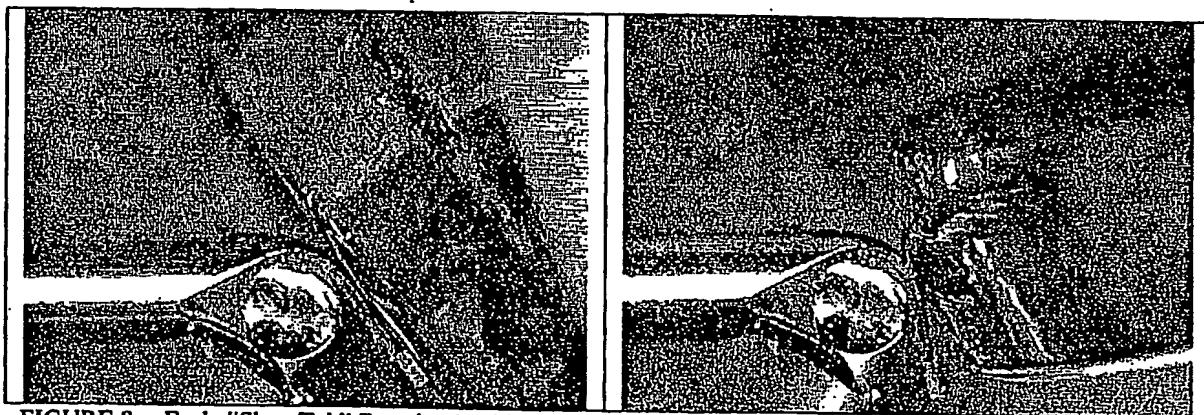


FIGURE 8a. Early "Shoe Tab" Forming Position

FIGURE 8b. Intermediate "Shoe Tab" Forming Position

- 4.2.4 Continue the forming of the "Shoe Tab" with a rotating motion of the tweezers until the inside surface of the "Shoe Tab" comes in contact with the tip of the "Return Tab" as shown in Figure 9a and then release the pressure on the tweezers. (This over-bending process will allow the formed "Shoe Tab" to spring back to a perpendicular position with respect to the axis of the Aspiration Tube" as shown in Figure 9b.)

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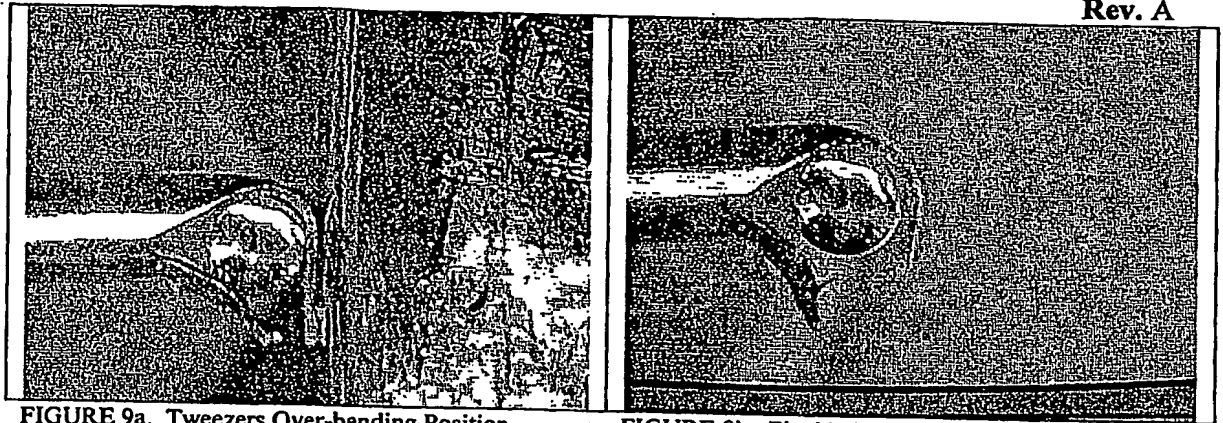


FIGURE 9a. Tweezers Over-bending Position

FIGURE 9b. Final "Shoe Tab" Spring Back Position

4.2.5 Ultrasonically clean the parts in Isopropyl Alcohol (IPA) for 15 minutes.

4.2.6 Allow the IPA to fully evaporate under a laminar flow hood before proceeding to the next steps.

4.3 APPLY LIQUID POLYIMIDE COATING TO FORM "SHOE"

4.3.1 Wear gloves for all assembly steps.

4.3.2 Attach a large bore tapered polyethylene dispensing tip to a 3cc polypropylene syringe and position the plunger at the 1cc marker to eliminate later direct contact of Liquid Polyimide [P/N 200076] with the rubber syringe plunger. (See Figure 10.)

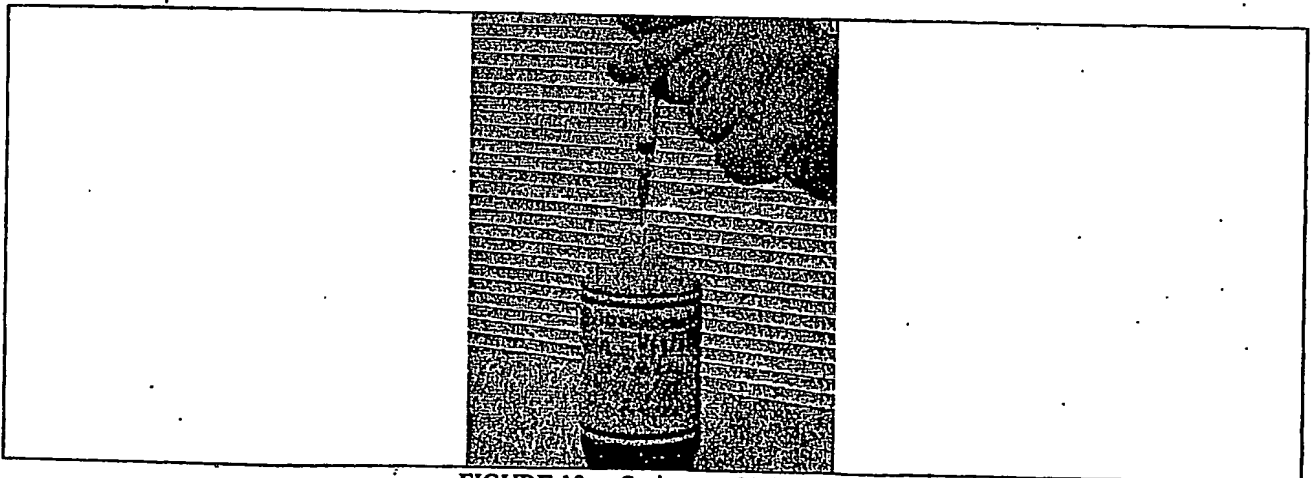


FIGURE 10. Syringe and Dispensing Tip Preparation

NEOMEDIX Corporation

Title: MI - Aspiration Tube with Return Electrode – Formed and Insulated MI 400020

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- 4.3.3 Insert the dispenser tip of the syringe into the bottle of Liquid Polyimide and extract approximately 1cc of Liquid Polyimide into the syringe body.
- 4.3.4 Dispense 1 drop of Liquid Polyimide onto the outside of a clean anti-static bag (or equivalent) as shown in Figure 11.

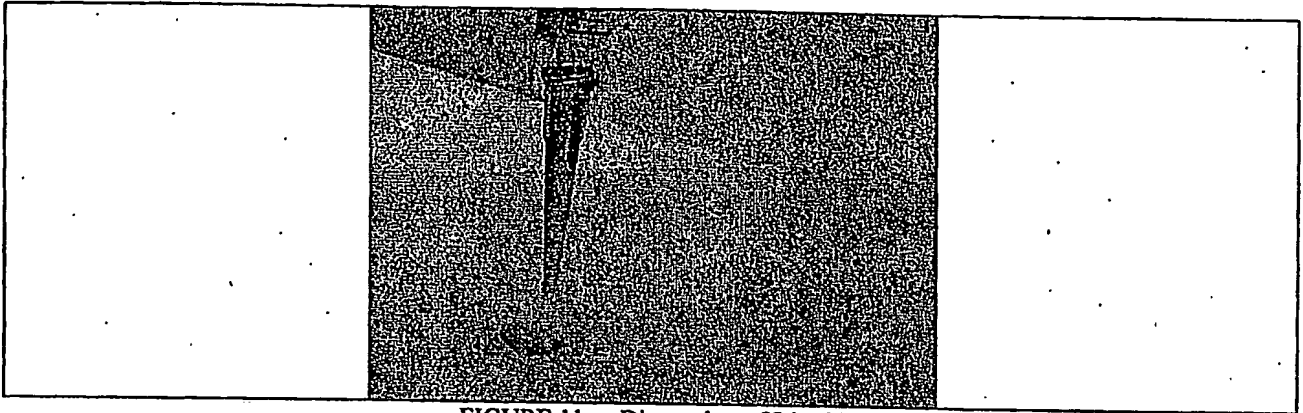


FIGURE 11. Dispensing of Liquid Polyimide Drop

- 4.3.5 Place a cap over the end of the syringe containing the Liquid Polyimide and store in a "dispenser tip downward" position to prevent contact of the Liquid Polyimide with the rubber syringe plunger.
- 4.3.6 Cut an approximate 2" length of 0.006" diameter 304V stainless steel wire [P/N 200083-03 or equivalent] with a clean wire cutter for subsequent use as a Liquid Polyimide applicator as shown in Figure 12.

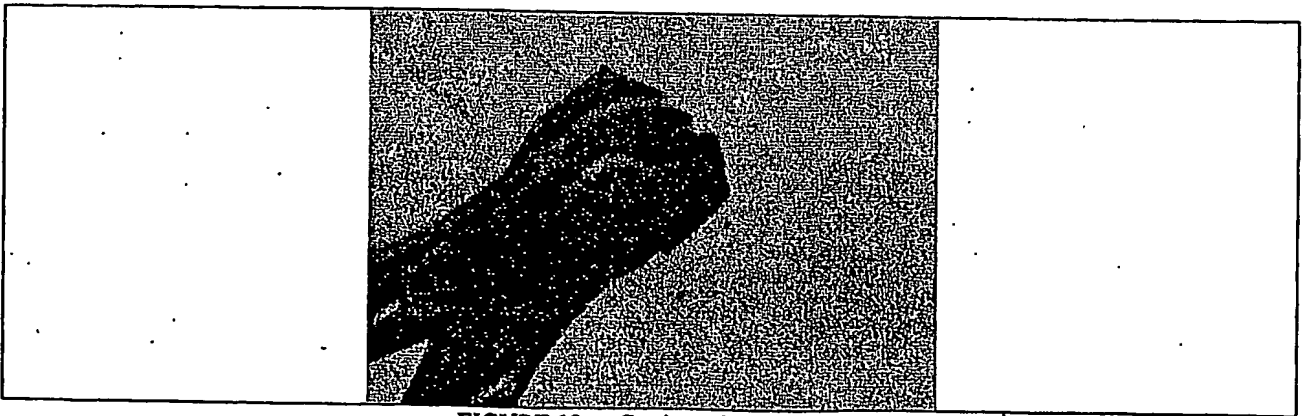


FIGURE 12. Cutting of Wire Applicator

NEOMEDIX Corporation

Title: MI - Aspiration Tube with Return Electrode – Formed and Insulated MI 400020

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- 4.3.7 Dip the tip of the 0.006" diameter applicator wire into the dispensed drop of Liquid Polyimide (dispense another fresh drop from the syringe when the surface of the previous drop becomes "gel-like") and pick up a minimal quantity of Liquid Polyimide as shown in Figure 13.

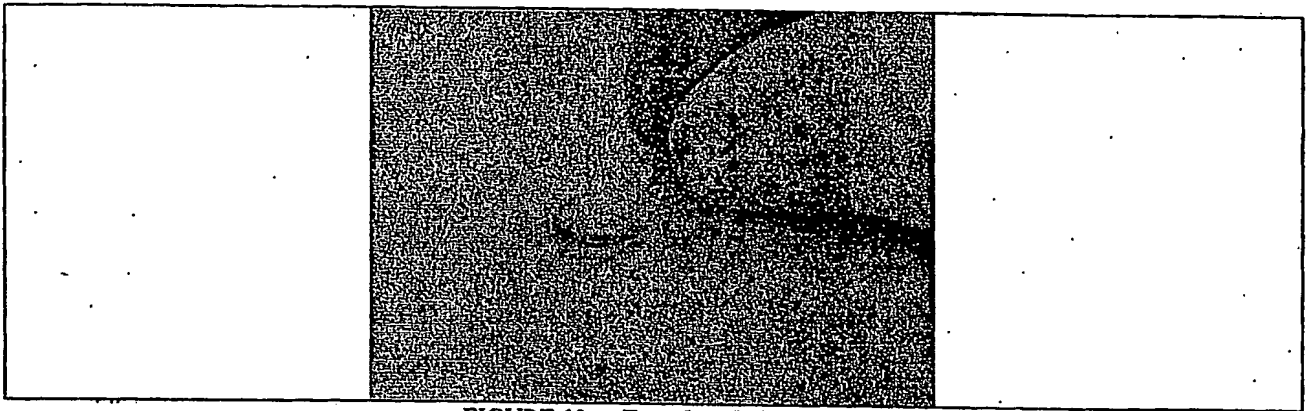


FIGURE 13. Transfer of Liquid Polyimide to Wire Applicator

- 4.3.8 Apply the small quantity of Liquid Polyimide from the wire applicator tip onto the "Shoe Tab" surface of the Aspiration Tube where indicated in Figure 14.

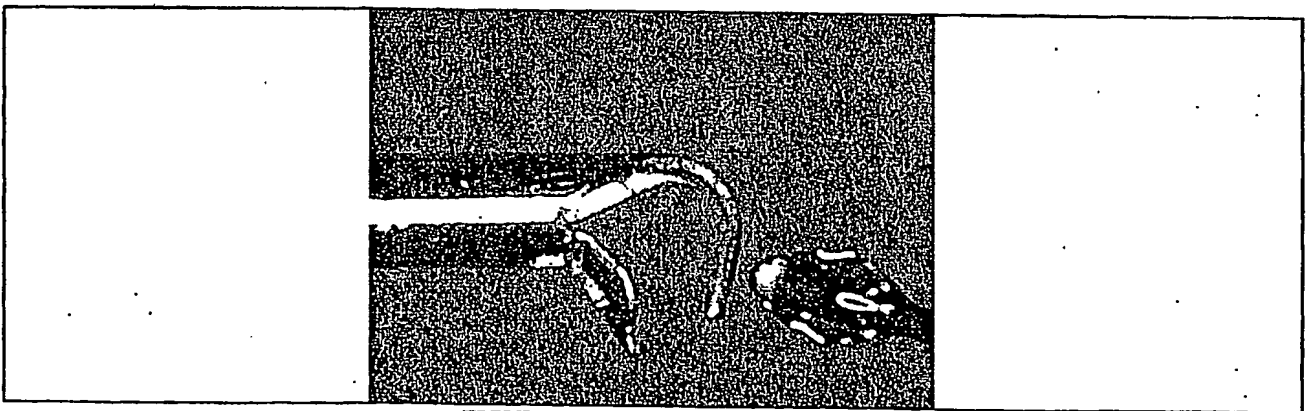


FIGURE 14. Transfer of Liquid Polyimide to "Shoe Tab"

- 4.3.9 Use the tip of the 0.006" wire to place Liquid Polyimide onto the distal pointed tip of the Aspiration Tube's "Foot" to ensure complete wetting of the pointed edge as shown in Figure 15.

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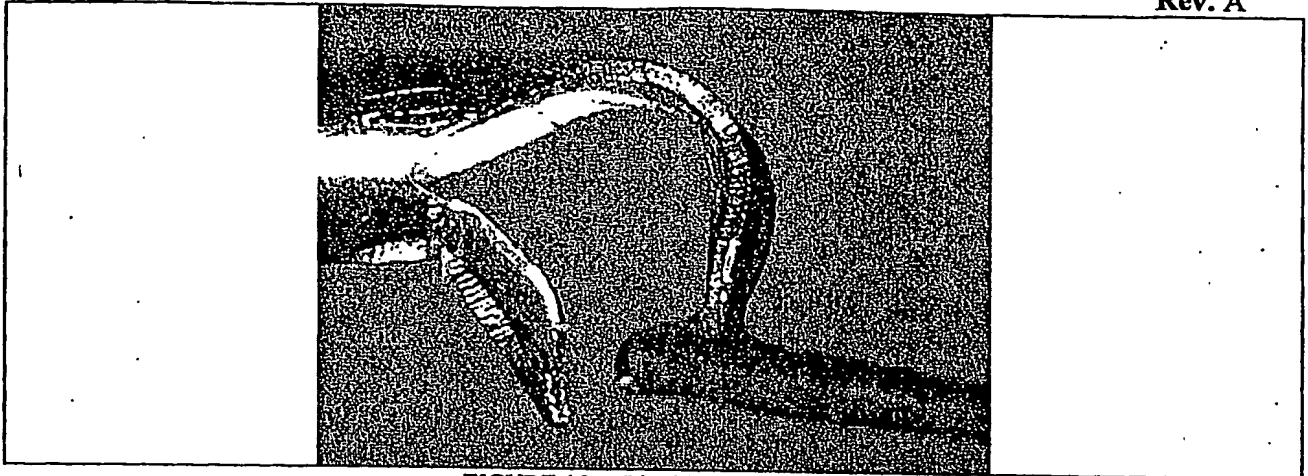


FIGURE 15. Liquid Polyimide Coating of "Shoe Tab's" Distal Pointed Tip

- 4.3.10 Distribute the Liquid Polyimide evenly over the Aspiration Tube's inner and outer diameter tube surface using the end of the 0.006" wire as a "paintbrush" as shown in Figure 16.

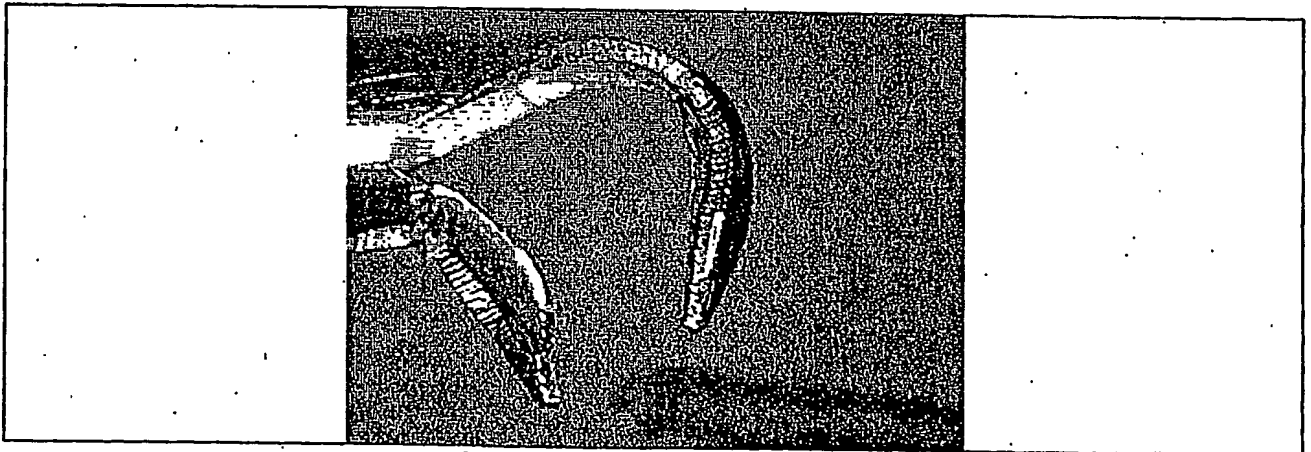


FIGURE 16. Uniform Distribution of Liquid Polyimide Coating on "Shoe Tab"

- 4.3.11 Place the Liquid Polyimide coated Aspiration Tube in the Aspiration Tube Holder being careful not to contact the uncured tip material. (See Figure 17.)

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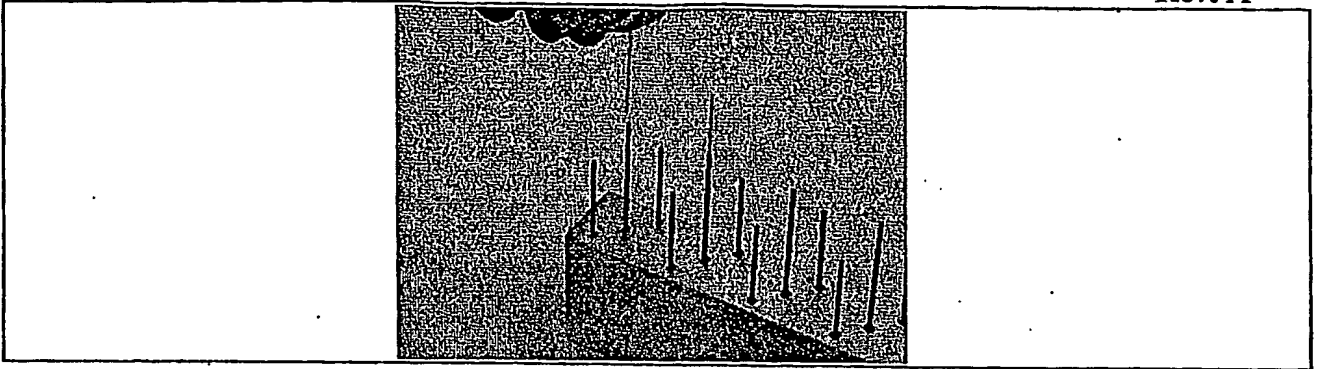


FIGURE 17. Placing Aspiration Tube Into Holder

4.4 CURING OF LIQUID POLYIMIDE COATING

- 4.4.1 Switch the NAPCO Model 5831 vacuum oven "ON" and set the "Temperature Controller" dial to the fully clockwise (highest temperature) position corresponding to a marked setting of "9". (See Figure 18.)

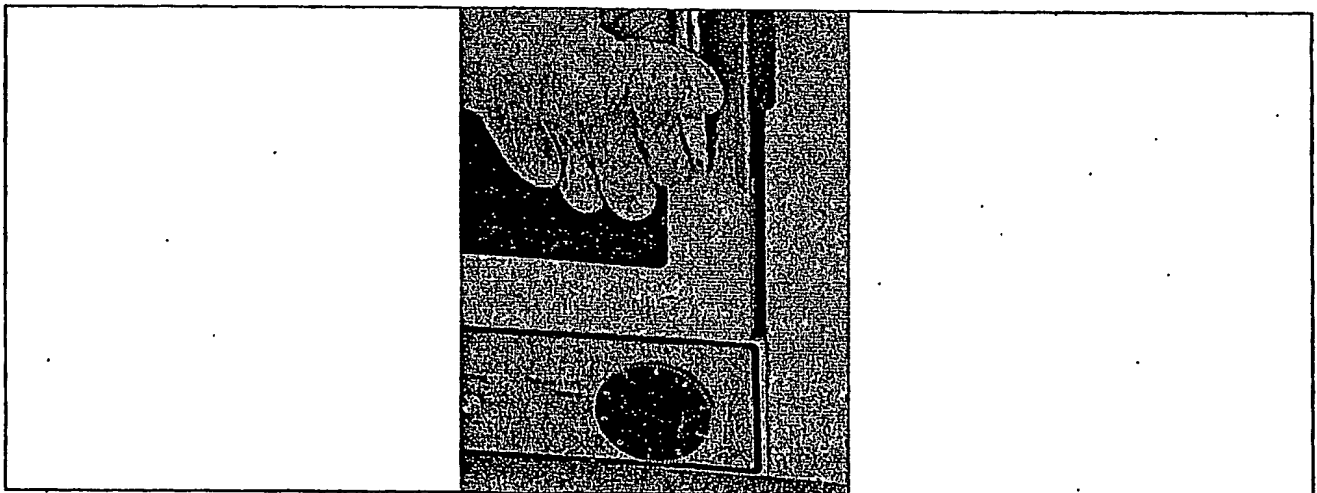


FIGURE 18. Vacuum Oven Setup

- 4.4.2 Allow the vacuum oven to come to temperature for a minimum of 2 hours with the door closed and vacuum applied prior to use.
- 4.4.3 Place the Aspiration Tube Holder(s) with Liquid Polyimide coated Aspiration Tubes into the vacuum oven as shown in Figure 19 and leave for 45-60 minutes with the door mostly closed and no vacuum applied to produce a full cure of the Liquid Polyimide coating.

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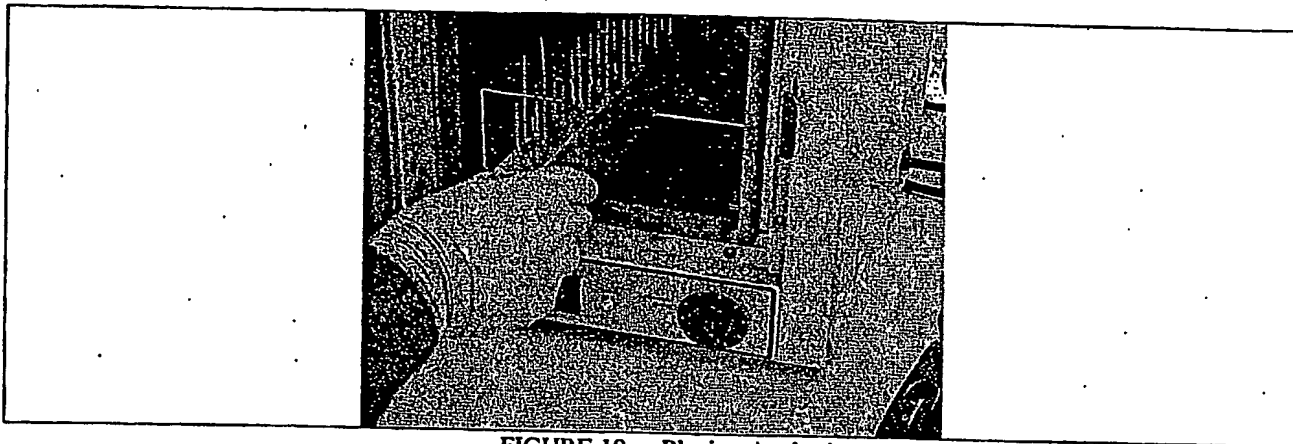


FIGURE 19. Placing Aspiration Tube Holder In Vacuum Oven

4.5 APPLY AND INSPECT 4-LAYER LIQUID POLYIMIDE COATING

- 4.5.1 Repeat all steps in Sections 4.3 and 4.4 until 4 layers of Liquid Polyimide have been applied and cured on the Aspiration Tube's "Shoe Tab".
- 4.5.2 Visually inspect the Liquid Polyimide coated region for coating defects and "reject" any parts that have bubbles, voids, sharp protrusions, or similar defects extending more than 0.001" from the surrounding surfaces.
- 4.5.3 Inspect the condition of the bent "Return Tab" and "Shoe Tab" features and "reject" any parts with defects including polyimide material on outer surface of "Return Tab", non-perpendicular bend of "Shoe Tab", asymmetrical bend angles of either tab, protruding metal burrs, and obstructions in the laser cut opening features.
- 4.5.4 Place all "Accepted" parts in clean, cushioned vials labeled with NeoMedix P/N, WO#, quantity, and date.
- 4.5.5 Place all "REJECTED" parts in clean, cushioned vials labeled with "REJECTED", NeoMedix P/N, WO#, quantity, and date. ("Rejected" parts should be placed in a designated QC Quarantine area for later review.)
- 4.5.6 Count the total number of "Accepted" and "Rejected" parts, record the data on the Work Order, return all documents to the Completed Work Order File, and log all "Accepted" materials into inventory.

Manufacturing Instructions

MI 400021

Title: MI – Assy, MicroSurgical Bipolar Handpiece

Rev. A

Prepared By: James Gerg

Release Level: Clinical

ECN No:

Release Approved By:

Date:

414-03

J. Lorenson

04/30/03

1.0 PURPOSE

Details the steps required for the assembly of the MicroSurgical Bipolar Handpiece Assembly, for personnel experienced in assembling disposable medical devices. The steps include threading the Luer Cap onto the 5cc Syringe Barrel reservoir to form a "Purge Chamber", aligning and bonding the Inner Functional Subassy to the Handpiece Body, securing the "Purge Chamber onto the tip of the device, and performing a final testing/cleaning procedure on the finished device.

2.0 TOOLS AND SUPPLIES

- Lesco Super Spot Max UV Cure System or equivalent
- EFD Fluid Dispenser (Model 1000XL-15psi, 2000XL-15psi, or equivalent)
- 25G x ½" Teflon-lined dispensing tips (EFD P/N 5125TLCS or equivalent)
- 27G x ½" SS dispensing tips (EFD P/N 5127-B or equivalent)
- Powder-Free Exam Gloves
- UV protective eyewear
- UV protective gloves, UVPS- NT Surgical Type, non-powdered
- Outer Cover Introducer Guide [NeoMedix P/N 300031]
- Sheath Alignment Fixture [NeoMedix P/N 300032]
- 200088 5cc Syringe Reservoir Barrel

3.0 MATERIALS

All materials are listed in the assembly drawing NeoMedix P/N 500021.

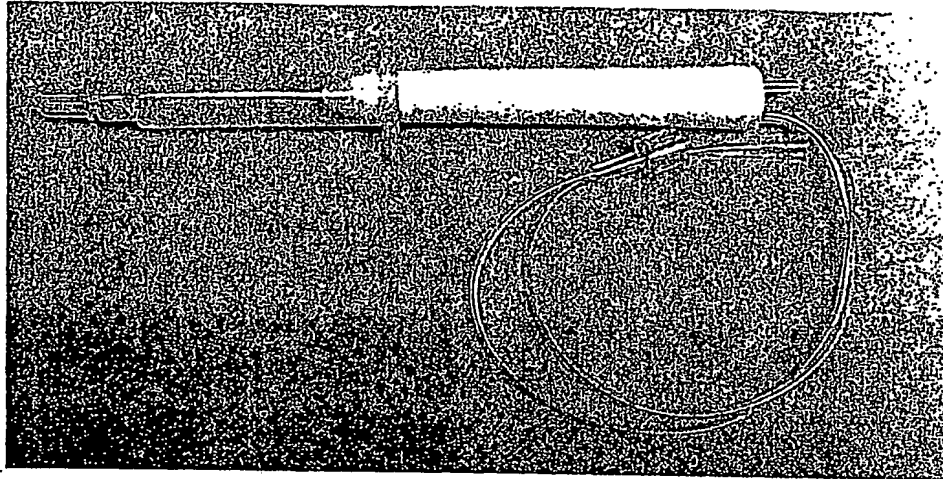
Additional referenced documents: QCTP 950011

NEOMEDIX Corporation

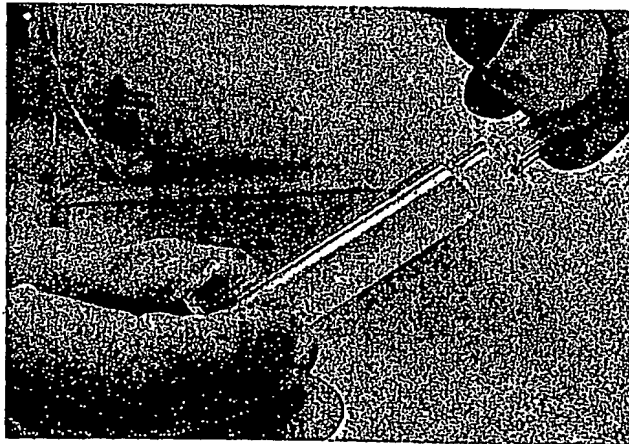
Title: MI - Assy, MicroSurgical Bipolar Handpiece

MI 400021

Rev. A

4.0 PROCEDURE**FIGURE 1. Finished Assembly**

- 4.1 THREAD LUER CAP ONTO BARREL TO FORM "PURGE CHAMBER"**
- 4.1.1 Where powder-free exam gloves for all steps.
 - 4.1.2 Secure the female luer thread of the Female Luer Threaded Cap [P/N 200087] onto the 5cc Syringe Reservoir Barrel's [P/N 200088] male luer tip as shown in **FIGURE 2**.

**FIGURE 2. Securing Female Luer Threaded Cap Onto Syringe**

4.2 INSERTING AND BONDING FUNCTIONAL INNER SUBASSY TO BODY

- 4.2.1 Insert the Outer Cover Introducer Guide through the central bore of the MicroSurgical Bipolar Handpiece Body [P/N 100065-02] as shown in **FIGURE 3**.

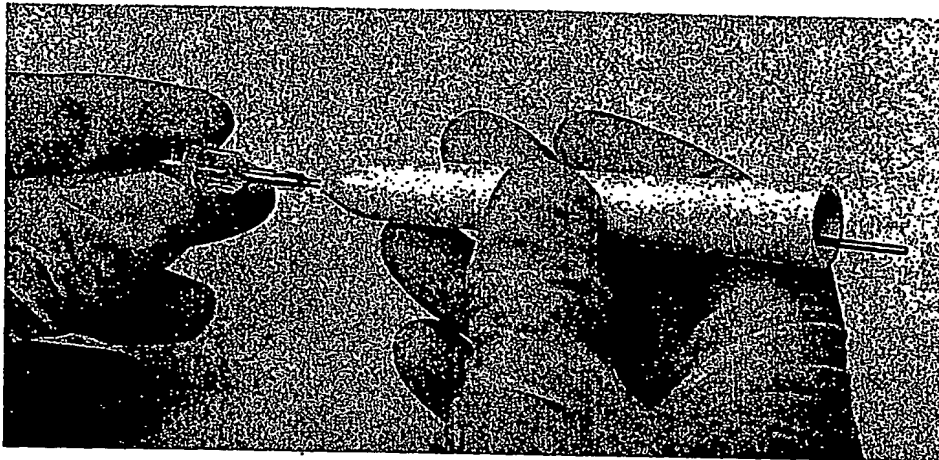


FIGURE 3. Insertion of Outer Cover Introducer Guide Thru Handpiece Body

- 4.2.2 Carefully insert the Functional Inner Subassy's [P/N 500029] delicate distal tip "Foot" feature fully into the inner diameter of the Outer Cover Introducer Guide as shown in **FIGURE 4**.

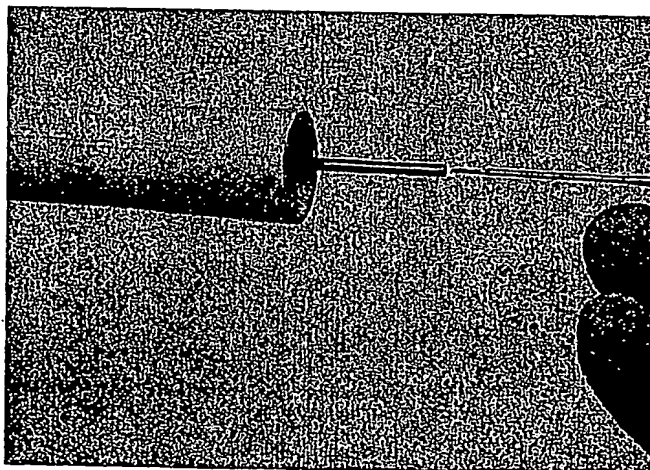


FIGURE 4. Insertion of Tip into Outer Cover Introducer Guide

Title: MI – Assy, MicroSurgical Bipolar Handpiece

MI 400021

Rev. A

- 4.2.3 Advance the assembly into the Handpiece Body leaving an approximate gap of 1" between the rear circular flange of the Inner Holder and the rear edge of the Handpiece Body.
- 4.2.4 Apply Cyclohexanone to the outside of the Inner Holder's circular flange.
- 4.2.5 Rotate the Inner Housing relative to the outer housing to align the circular flange features with the Handpiece Body features.
- 4.2.6 Advance the assembly into the Handpiece Body until there is an approximate gap of 0.010" between the rear circular flange of the Inner Holder and the rear edge of the Handpiece Body as shown in **FIGURE 5**.

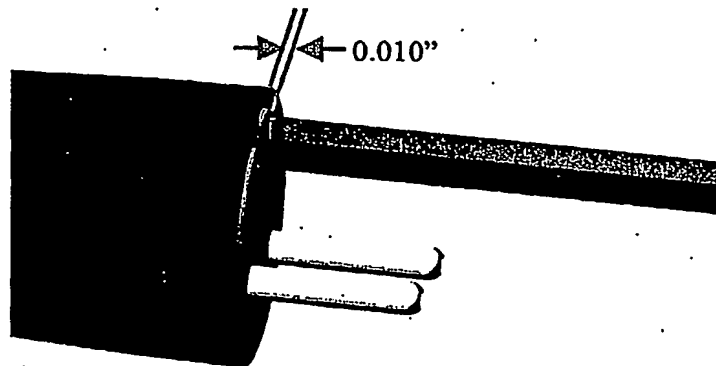


FIGURE 5. Location of Flange Relative to Rear Edge of Handpiece Body

- 4.2.7 Place the handpiece subassembly into the Sheath Alignment Fixture [NeoMedix P/N 300032] being careful not to damage the subassembly's delicate distal tip as shown in **FIGURE 6**. (Note: The pair of Electrical Contact Pins must be fully engaged in the fixture's lower alignment bores.)

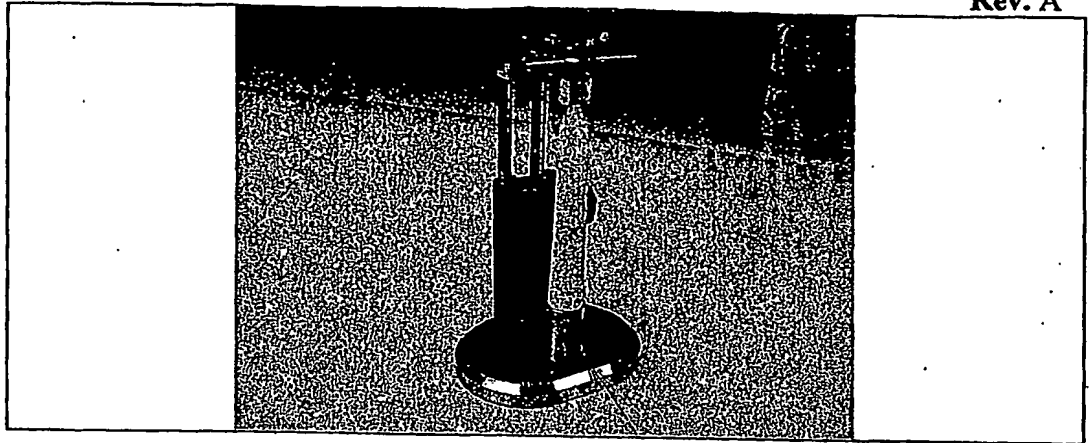


FIGURE 6. Subassembly Placement in Sheath Alignment Fixture

- 4.2.8 Compress the fixture until the distal tapered portion of the Handpiece Body contacts the fixture's white centering feature and secure the alignment of the assembly with the cross alignment pin as shown in **FIGURE 7**.

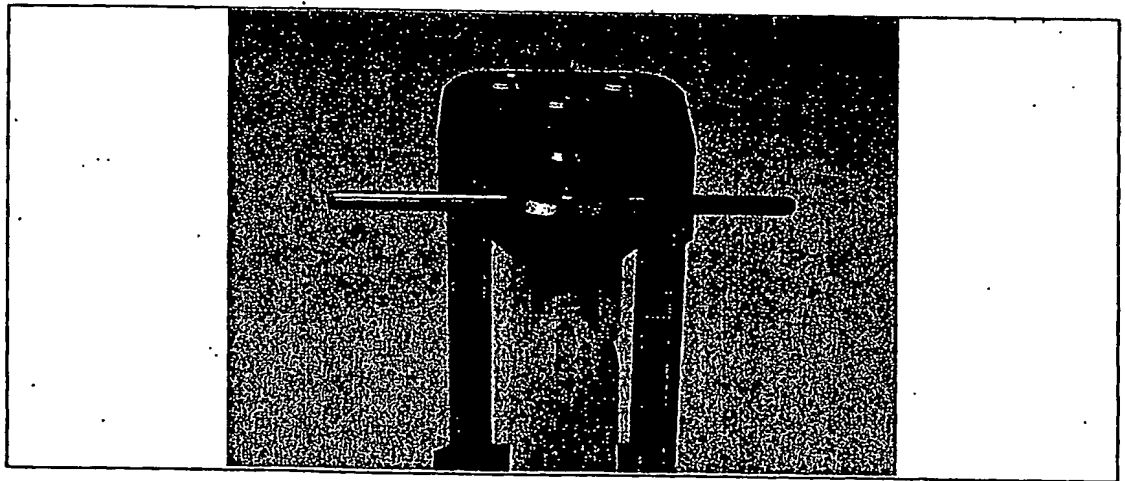


FIGURE 7. Compressing Fixture and Engaging Cross-Alignment Pin

- 4.2.9 Use the dispensing tip to evenly distribute Loctite 3031 UV adhesive around the circumference of the Handpiece Body-to-Inner Holder bonding interface as shown in **FIGURE 8**. (Note: Cure adhesive rapidly with UV light source to prevent adhesive migration from the bond site to the Handpiece Body.)

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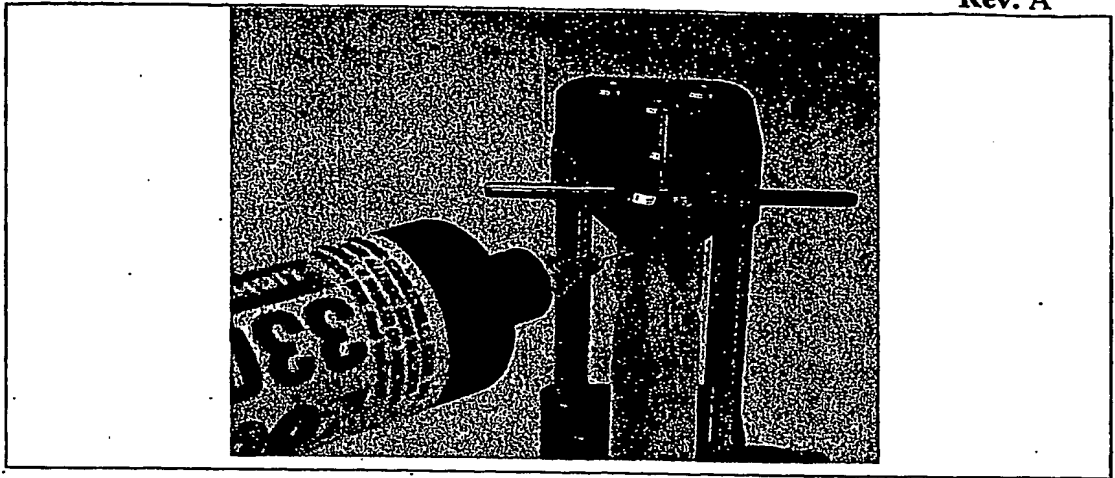


FIGURE 8. Apply Adhesive to Distal Handpiece Body-to-Inner Holder Interface

- 4.2.10 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the tip of a single light guide positioned approximately 3" from the bond site.
- 4.2.11 Use the dispensing tip to distribute adhesive to the rear flange interface of the Handpiece Body and the Inner Holder where the tubing exits the handpiece as shown in **FIGURE 9**. (Note: The objective is to completely seal the interface to ensure that there are no remaining leak paths between the inside and outside of the Handpiece Body.)

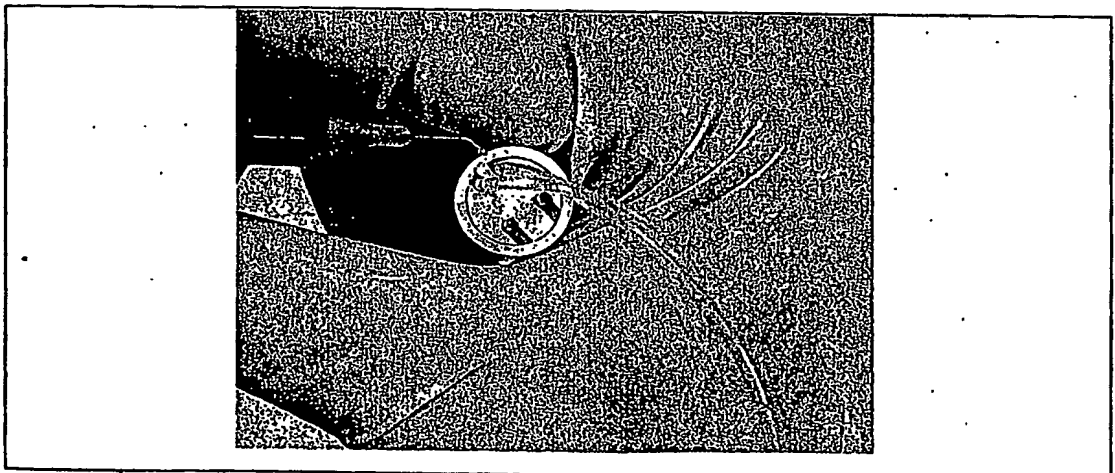


FIGURE 9. Apply Adhesive to Seal the Rear Handpiece Body-to-Inner Holder Interface

Title: MI - Assy, MicroSurgical Bipolar Handpiece

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4.2.12 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the tip of a single light guide positioned approximately 3" from the bond site.

4.3 PERFORM QCTP 950011- FINAL TEST

4.4 SEATING PURGE CHAMBER ONTO HANDPIECE BODY

4.4.1 Carefully insert the Purge Chamber (previously assembled in Section 4.1) over the delicate distal handpiece tip and firmly seat onto the Handpiece Body as shown in **FIGURE 10**.

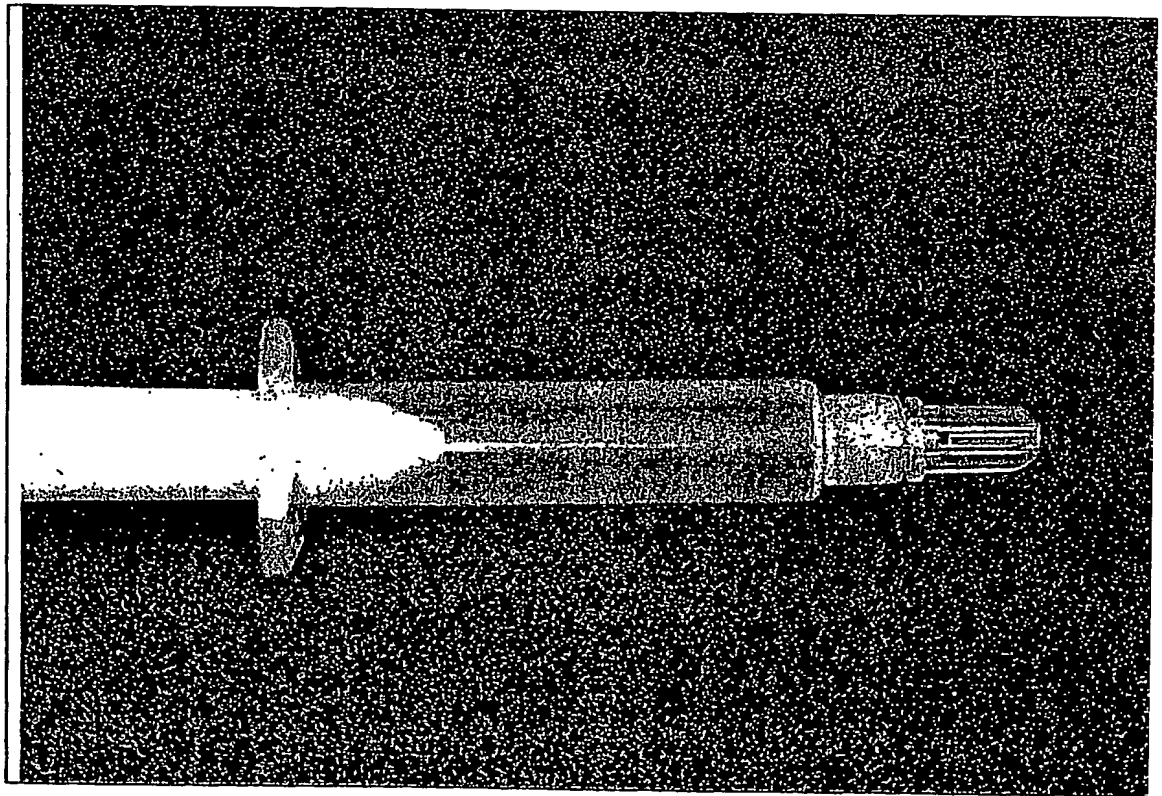


FIGURE 10. Seating Purge Chamber Onto Handpiece Body

NEOMEDIX Corporation

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MI 400021

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4.5 INSPECTING THE ASSEMBLY AND COMPLETING THE WORK ORDER

- 4.5.1 Verify that the axis of the "Foot" feature at the distal tip of the Aspiration Tube is rotationally aligned within 30° of the Handpiece Body's Orientation Indicator Notch. ("REJECT" any assemblies that do not conform to this requirement.)
- 4.5.2 Verify that the "Foot" feature has not been damaged or deformed during the handling of the assembly. ("REJECT" any assemblies that have damaged or deformed features.)
- 4.5.3 Verify that the axis of the Aspiration Tube measured closest to the distal tip has a maximum run out of 0.100" measured against the rotational center of the tapered Handpiece Body surfaces. ("REJECT" any assemblies that do not conform to this requirement.)
- 4.5.4 Place all "Accepted" assemblies tip downward into a suitable protective holder means (protects the assemblies from damage and collection of debris) labeled with NeoMedix P/N, WO#, quantity, and date.
- 4.5.5 Place all "REJECTED" assemblies in clean bins labeled with "REJECTED", NeoMedix P/N, WO#, quantity, and date. ("Rejected" assemblies should be placed in a designated QC Quarantine area for later review.)
- 4.5.6 Count the total number of "ACCEPTED" and "REJECTED" assemblies, record the data on the Work Order.

NEOMEDIX
Corporation

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San Juan Capistrano, CA. 92675

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Manufacturing Instructions

MI 400029

Title: MI – Functional Inner Subassy

Rev. A

Prepared By: James Gerg

Release Level: Clinical

ECN No:
415-03

Release Approved By:

J. Lorenson

Date:
05/01/03

1.0 PURPOSE

Details the steps required for the assembly of the Functional Inner Subassy for personnel experienced in assembling disposable medical devices. The steps include bonding two electrical contact pins to the Inner Holder, bonding the Inner Unsupported Subassembly to the Inner Holder, soldering the Aspiration Tube and Electrode Wire to the contact pins, and bonding the Irrigation and Aspiration Tubing into the rear guide channels of the Inner Holder.

2.0 TOOLS AND SUPPLIES

- Lesco Super Spot Max UV Cure System or equivalent
- 23G x ½" SS dispensing tips (EFD P/N 5123-B or equivalent)
- 22G (blue) tapered polyethylene dispensing tips (EFD P/N 5122(R)TT-B or equivalent)
- Inner Holder – Sheath Alignment Fixture [NeoMedix P/N 300033]
- Rotating Inner Holder Fixture [NeoMedix P/N 300031]

3.0 MATERIALS

All materials are listed in the assembly drawing NeoMedix P/N 500029.

Additional referenced documents: N/A.

Confidential

CONTROL DOCUMENT

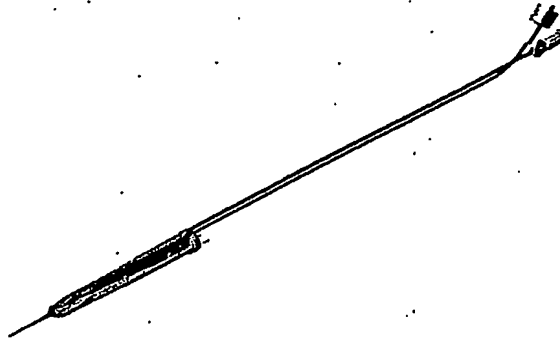
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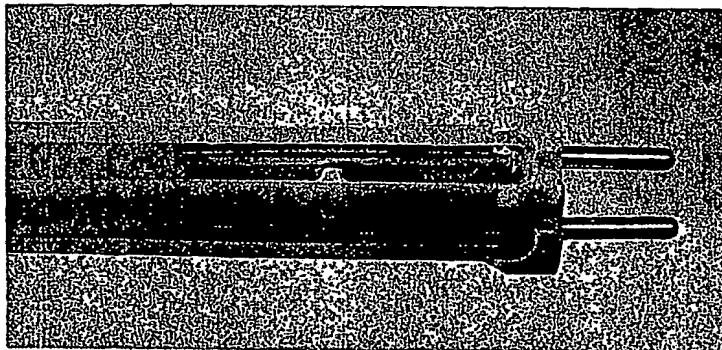
Title: MI - Functional Inner Subassy

MI 400029

Rev. A

4.0 PROCEDURE**FIGURE 1. Finished Assembly****4.1 BONDING CONTACT PINS TO INNER HOLDER**

- 4.1.1 Insert the blunt, square ends of 2 Electrical Contact Pins [P/N 200082] into the rear holes of the Inner Holder [P/N 100067] and position axially against the distal most (pin stop) ledge as shown in FIGURE 2.

**FIGURE 2. Positioning Contact Pins**

- 4.1.2 Apply Loctite 3301 UV Cure Adhesive [P/N 200005] using two 3-second dispense cycles at 15psi with a 25G Teflon-lined dispensing tip to each of the 2 bond sites where the Contact Pins enter the inner face of the flange as shown in FIGURE 3. (Note: Contact Pins should be parallel to each other and in contact with the molded pin stop surface prior to bonding. Apply a seating force if necessary to ensure correct positioning.)

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Title: MI – Functional Inner Subassy

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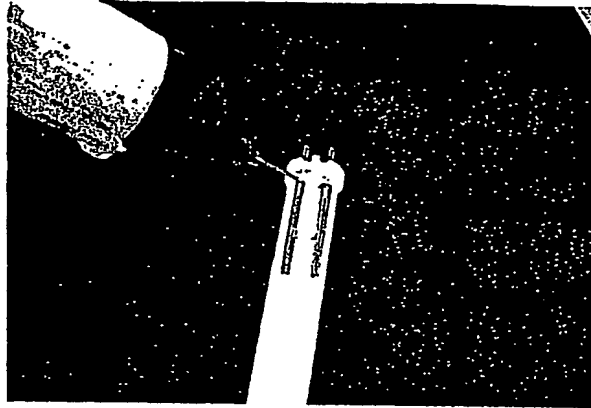


FIGURE 3. Bonding Contact Pins to Inner Flange Surface.

- 4.1.3 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the working end of a single light guide positioned approximately 3" from the bond site.
- 4.1.4 Apply Loctite 3301 UV Cure Adhesive [P/N 200005] using a single 3-second dispense cycle at 15psi with a 25G Teflon-lined dispensing tip to each of the 2 bond sites where the Contact Pins exit the proximal (outer) flange face of the Inner Holder as shown in FIGURE 4. (Note: Adhesive is not allowed on the outer diameter of the Inner Holder's rear flange. Wipe off any excess liquid adhesive on this surface prior to curing.)

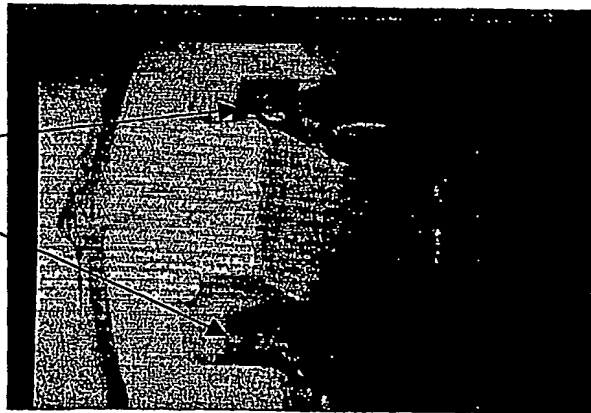
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FIGURE 4. Bonding Contact Pins to Outer Flange Surface

NEOMEDIX Corporation

Title: MI – Functional Inner Subassy

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Rev. A

- 4.1.5 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the working end of a single light guide positioned approximately 3" from the bond site.

4.2 BOND INNER UNSUPPORTED SUBASSY TO INNER HOLDER

- 4.2.1 Load the Inner Holder into the Inner Holder – Sheath Alignment Fixture [NeoMedix P/N 300033] with the fixture resting parallel to the work surface by inserting the contract pins into the fixture's base socket as shown in FIGURE 5.

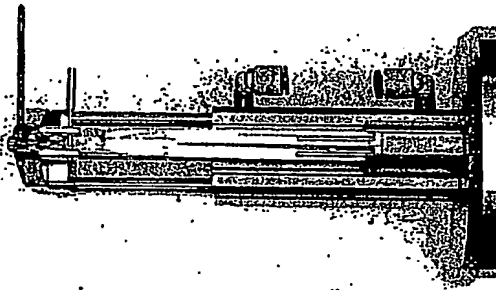


FIGURE 5. Loading Inner Holder Into Fixture

- 4.2.2 Insert the Irrigation Sheath section of the Inner Unsupported Subassy into the spring-loaded upper guide fixture mechanism with it's D-flat feature in contact with the fixture's rotational keying element and secure in place with the distal cross-pin as shown in FIGURE 6.

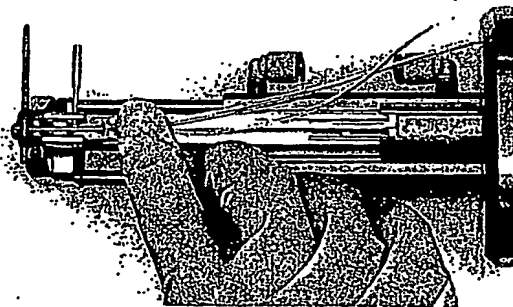


FIGURE 6. Loading Inner Unsupported Subassy Into Fixture

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- 4.2.3 Compress the fixture's cylinder guided mechanism to fully seat the D-flange of the Inner Unsupported Subassy into the mating counterbore of the Inner Holder and engage the fixture's proximal cross alignment pin as shown in FIGURE 7. (Note: Compress the D-shaped flange of the Irrigation Sheath Billet into the D-shaped counterbore of the Inner Holder and verify the rotational alignment of the flange to the counterbore such that the D-shaped feature edges are parallel to each other and the irrigation holes are facing directly upwards.)

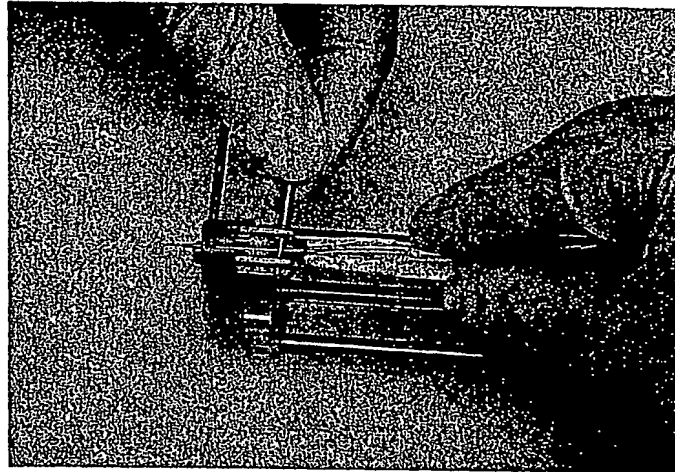


FIGURE 7. Engaging Proximal Cross-Pin to Align Inner Holder to Inner Unsupported Subassy

- 4.2.4 Firmly seat tubing into Inner Holder channels as shown in FIGURE 8.

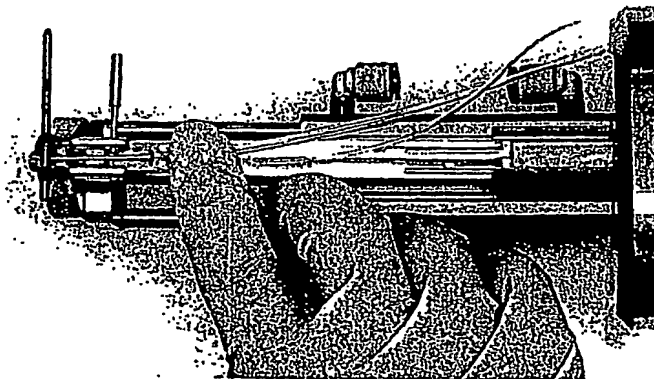


FIGURE 8. Seating Tubing Into Inner Holder Channels

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- 4.2.5 Apply Loctite 3301 UV Cure Adhesive [P/N 200005] using a single 3-second dispense cycle at 15psi with a 23G dispensing tip to the D-flange to Inner Holder interface while holding both tubing segments down in channels of the Inner Holder as shown in FIGURE 9.

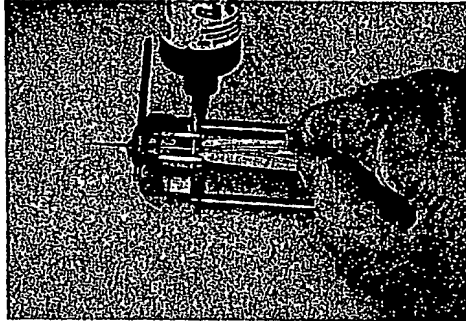


FIGURE 9. Bonding Distal D-flange Interface of Inner Unsupported Subassy to Inner Holder

- 4.2.6 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the working end of a single light guide positioned approximately 3" from the bond site
- 4.2.7 Apply Loctite 3301 UV Cure Adhesive [P/N 200005] using a single 3-second dispense cycle at 15psi with a 23G dispensing tip to each of the Inner Holder's two tubing guide ramps and press both the irrigation tubing and aspiration tubing firmly into the guide ramp channels as shown in FIGURE 10. (Note: Separate the Electrode Wire and the Aspiration Tube onto opposite sides of the Inner Holder's central "dorsal fin" tab feature prior to proceeding to the next assembly steps.)

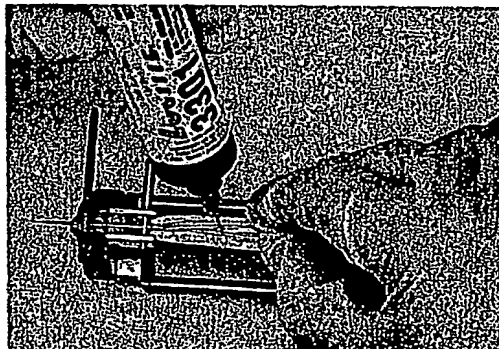


FIGURE 10. Bonding Tubing Into Channels of Inner Holder

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- 4.2.8 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the working end of a single light guide positioned approximately 3" from the bond site.
- 4.2.9 Apply Loctite 3301 UV Cure Adhesive [P/N 200005] using as many as necessary 3-second dispense cycles at 15psi with a 23G dispensing tip to cover the entire region between the D-shaped flange interface and the proximal edge of the tubing guide ramps with adhesive as shown in FIGURE 11.

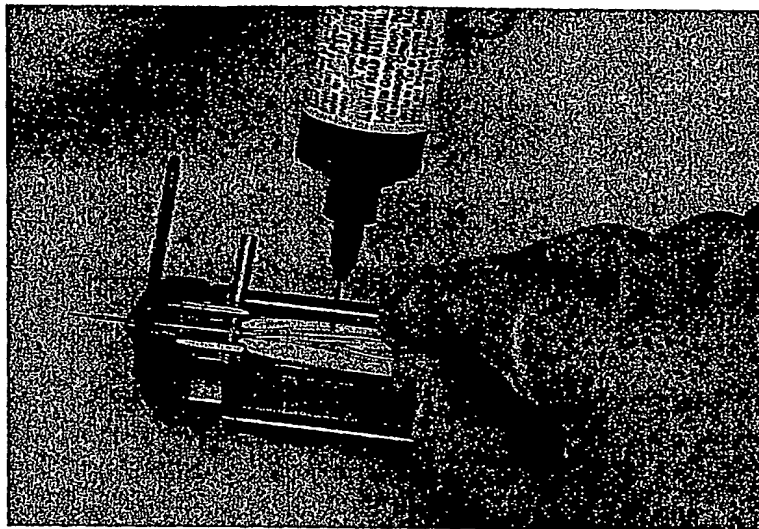


FIGURE 11. Over-bonding Tubing-to-Inner Holder Interface

- 4.2.10 Cure adhesive with two 6-second minimum cycles of the Lesco SuperSpot Max UV Cure System set to minimum power with the working end of a single light guide positioned approximately 3" from the bond site. (Note: Make sure to rotate assembly and/or light guide wand during and between cycles to ensure complete adhesive cure in all locations.)

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4.3 SOLDERING TO THE ELECTRICAL CONTACT PINS

- 4.3.1 Place the Electrical Contact Pins into the retention holes of the Rotating Inner Holder Fixture [P/N 300031] as shown in FIGURE 12.

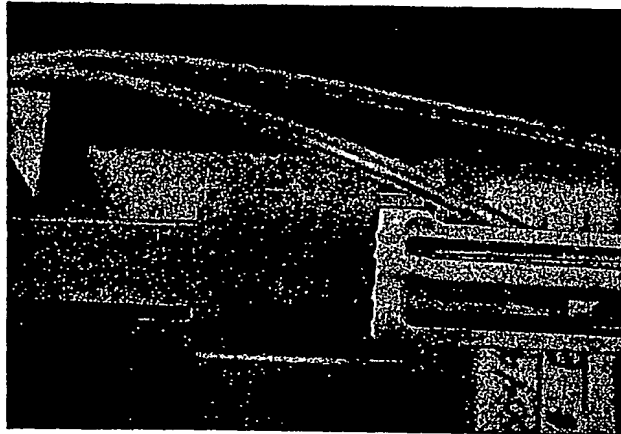


FIGURE 12. Loading Subassembly Into Rotating Inner Holder Fixture

- 4.3.2 Grasp the proximal (gold-plated) ends of the Electrode Wire and Aspiration Tube with tweezers and position them so that they make stress free contact with the outer diameter of the Electrical Contact Pins as shown in FIGURE 13.

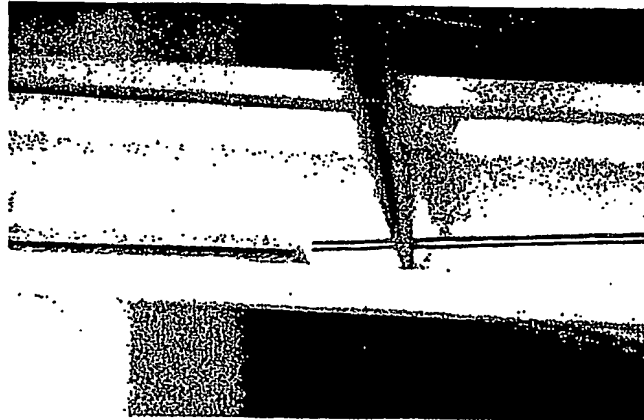


FIGURE 13. Inserting Aspiration Tube and Electrode Wire Into Contact Pins

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- 4.3.3 Dispense Solder Paste [P/N 200069] using two 2-second dispense cycles at 30psi with a 22G (blue) tapered dispensing tip onto the outer diameter of each of the 2 Electrical Contact Pins as shown in FIGURE 14.

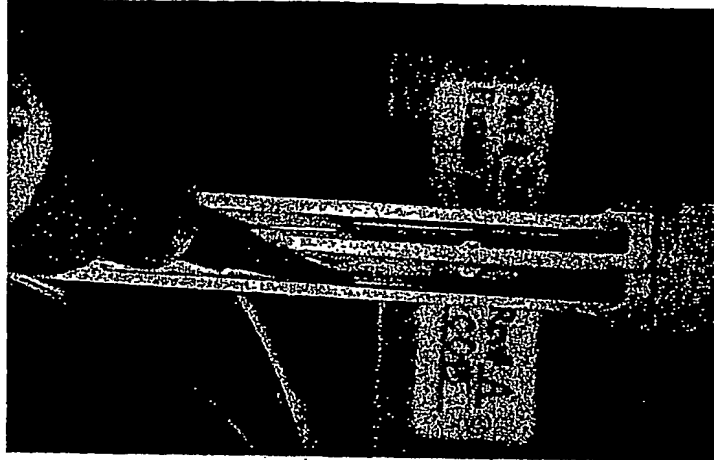


FIGURE 14. Dispensing Solder Paste

- 4.3.4 Use tweezers to hold the Electrode Wire in contact with the outer diameter surface of the Contact Pin and solder in place with a soldering tip temperature setting of 700°F/371°C. (Note: Reheat solder connection with soldering tip if necessary to eliminate dull solder joints or redistribute molten solder to form a "solder bridge" between the part surfaces. Do not allow soldering tip to stay in contact with the Contact Pin for too long such that the Inner Holder plastic material would melt.)
- 4.3.5 Use tweezers to hold the Aspiration Tube in contact with the outer diameter surface of the other Contact Pin and solder in place with a soldering tip temperature setting of 700°F/371°C. (Note: Reheat solder connection with soldering tip if necessary to eliminate dull solder joints or redistribute molten solder to form a "solder bridge" between the part surfaces. Do not allow soldering tip to stay in contact with the Contact Pin for too long such that the Inner Holder plastic material would melt.)
- 4.3.6 Pull on both solder joints lightly with tweezers to verify good solder joint strength. Re-apply solder tip per Steps 4.3.4 or 4.3.5 if necessary to repair separated solder joint(s).

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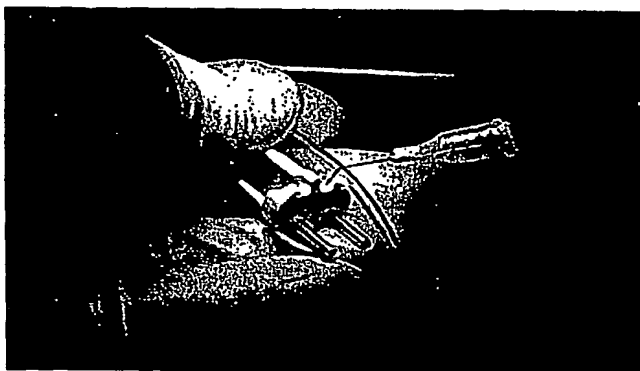
Title: MI – Functional Inner Subassy

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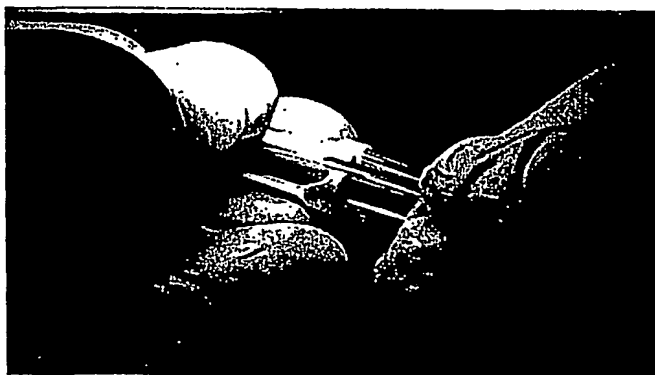
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4.4 STRAIN RELIEF BONDING TUBING TO INNER HOLDER

- 4.4.1 Apply Loctite 3301 UV Cure Adhesive [P/N 200005] using two 3-second dispense cycles at 15psi with a 23G dispensing tip to each of the two solder joint areas and cure immediately with UV light directed radially and thru the holes in the contact pins radiused end to completely seal the inner diameters of the contact pins.
- 4.4.2 Apply Loctite 3301 UV Cure Adhesive [P/N 200005] using a 3-second dispense cycle at 15psi with a 25G Teflon-lined dispensing tip to each of the two notches in the rear flange of the Inner Holder as shown in FIGURE 15.

**FIGURE 15. Applying Adhesive to Tubing Notches**

- 4.4.3 Place both the Irrigation and Aspiration Tubing into the tubing notches of the Inner Holder and align parallel to the central axis of the Inner Holder using light tension on the tubing as shown in FIGURE 16.

**FIGURE 16. Aligning Tubing to Inner Holder**

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- 4.4.4 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the working end of a single light guide positioned approximately 3" from the bond site.
- 4.4.5 Remove assembly from Rotating Inner Holder Fixture.

4.5 INSPECTING THE SUBASSEMBLY

- 4.5.1 Verify that the axis of the "Foot" feature at the distal tip of the Aspiration Tube is rotationally aligned within 20° of perpendicular to the flat features of the Inner Holder. ("REJECT" any assemblies that do not conform to this requirement.)
- 4.5.2 Verify that the "Foot" feature has not been damaged or deformed during the handling of the assembly. ("REJECT" any assemblies that have damaged or deformed features.)
- 4.5.3 Verify that the axis of the Aspiration Tube measured near the distal tip has a maximum run out of 0.100" measured against the rotational central axis of the Inner Holder's rear flange outer diameter and the Irrigation Sheath's 0.077" nominal diameter step feature. ("REJECT" any assemblies that do not conform to this requirement.)
- 4.5.4 Place all "Accepted" assemblies tip downward into a suitable protective holder means (protects the assemblies from damage and collection of debris) labeled with NeoMedix P/N, WO#, quantity, and date.
- 4.5.5 Place all "REJECTED" assemblies in clean bins labeled with "REJECTED", NeoMedix P/N, WO#, quantity, and date. ("REJECTED" assemblies should be placed in a designated QC Quarantine area for later review.)
- 4.5.6 Count the total number of "ACCEPTED" and "REJECTED" parts, record the data on the Work Order, and return all documents to the Completed Work Order File.

Manufacturing Instructions

MI 400032

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Rev. A

Prepared By: James Gerg

Release Level: Clinical

ECN No:
416-03

Release Approved By:

J. Souren

Date:
05/06/03

1.0 PURPOSE

Details the steps required for the assembly of the Inner Unsupported Subassy, for personnel experienced in assembling disposable medical devices. The steps include cutting the Irrigation and Aspiration tubing pigtails, bonding fittings to the pigtails, bonding the Irrigation Tubing Pigtail into the Irrigation Sheath Subassy, positioning and bonding the Aspiration Tube to the Irrigation Sheath Subassy, sealing the proximal end of the Aspiration Tube, piercing the Aspiration Tubing Pigtail with a sharp needle introducer, positioning and bonding the Aspiration Tubing Pigtail, sealing the Aspiration Tubing Pigtail pierce location, positioning and bonding the Titanium Electrode Wire to the Aspiration Tube and inspecting the finished subassemblies.

2.0 TOOLS AND SUPPLIES

- UV Cure System (Lesco Super Spot Max or equivalent)
- EFD Fluid Dispenser (Model 1000XL-15psi, 2000XL-15psi, or equivalent)
- 25G x 1/2" Teflon-lined dispensing tips (EFD P/N 5125TLCS or equivalent)
- 23G x 1/2" SS dispensing tips (EFD P/N 5123-B or equivalent)
- 27G x 1/2" SS dispensing tips (EFD P/N 5127-B or equivalent)
- 30G x 1/2" SS dispensing tips (EFD P/N 5130-B or equivalent)
- 32G x 1/4" SS dispensing tips (EFD P/N 5132-1/4-B or equivalent)
- 19G x 1" Surgical Sharp Needle
- #10 Scalpel Blade
- Scalpel Blade Handle
- Irrigation Sheath Holder [NeoMedix P/N 300030]
- Tip Alignment Fixture [NeoMedix P/N 300023]

3.0 MATERIALS

All materials are listed in the assembly drawing NeoMedix P/N 500032.
Additional referenced documents: NeoMedix P/Ns 100068 and P/N 100060-drawings

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4.0 PROCEDURE

FIGURE 1. Finished Assembly

4.1 **FORM IRRIGATION AND ASPIRATION PIGTAILS WITH FITTINGS**

- 4.1.1 Measure and mark a distance of 13.42" from the edge of a rigid cutting surface (e.g. Polypropylene sheet on clean room table).
- 4.1.2 Cut from a coil a piece of 0.050"ID x .090" Microbore Tygon [P/N 200064-05] using a sharp #10 scalpel blade into square-ended, 13.42" (± 0.25 ") lengths as shown in FIGURE 2. (Refer to NeoMedix P/N 100060 drawing).

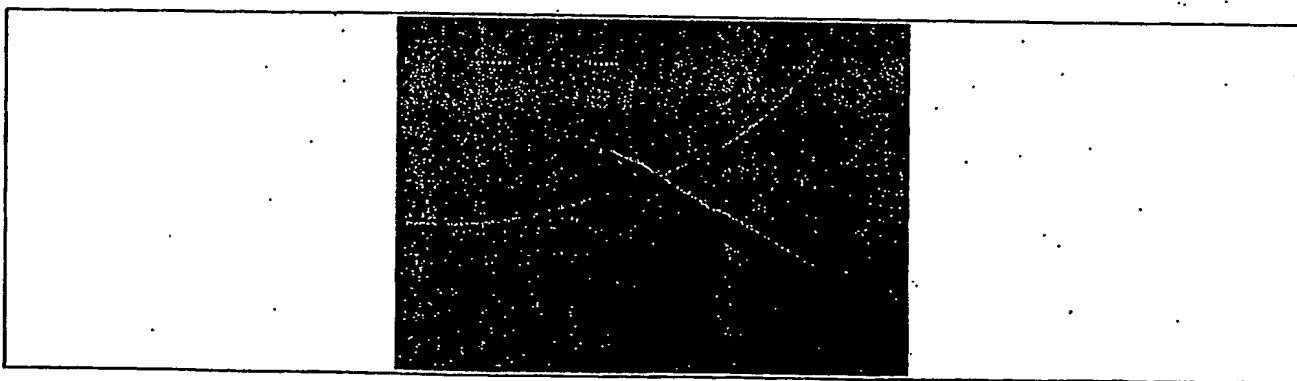


FIGURE 2. Cutting 0.050"ID x .090" Microbore Tygon.

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- 4.1.3 Apply and evenly distribute 2-drops of Loctite 3301 UV Adhesive [P/N 200005] using a 27G SS dispensing tip with a 1-second dispense cycle at 15psi around the outer circumference of one end of the cut-to-length 0.050"ID x .090"OD (hereafter referred to as "Irrigation Tubing Pigtail") approximately 0.050" from the end of the tubing as shown in **FIGURE 3**.

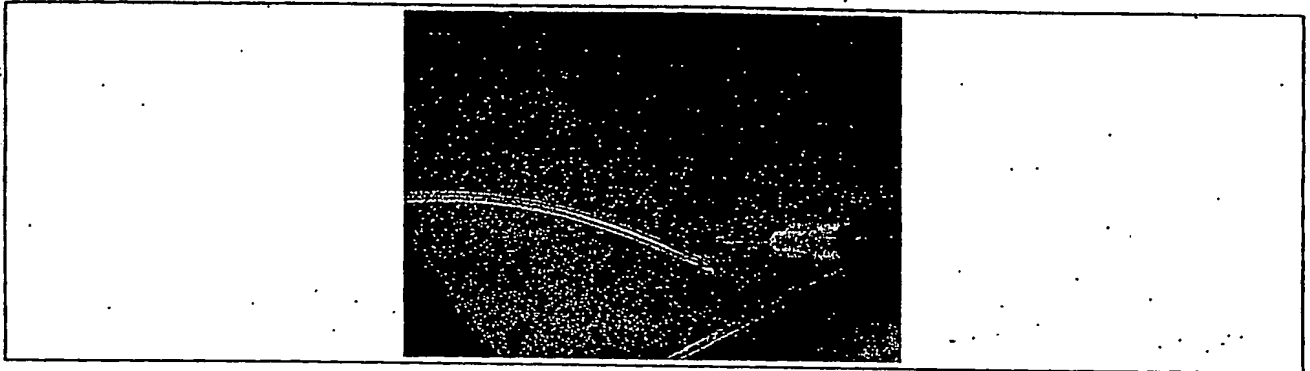


FIGURE 3. Applying Adhesive to Irrigation Tubing Pigtail

- 4.1.4 Fully insert the adhesive coated end of the Irrigation Tubing Pigtail into the inner bore diameter of the Female Luer Lock Fitting [P/N 200063] as shown in **FIGURE 4**.

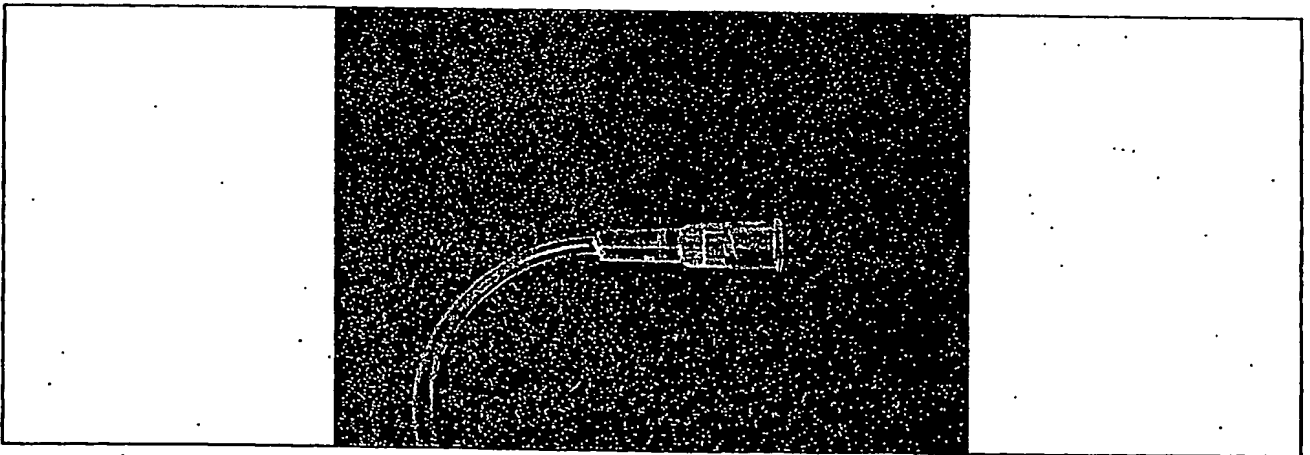


FIGURE 4. Bonding Irrigation Tubing Pigtail to Female Luer Fitting

- 4.1.5 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the tip of a single light guide positioned approximately 3" from the bond site.

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- 4.1.6 Measure and mark a distance of 12.93" from the edge of a rigid cutting surface (e.g. Polypropylene sheet on clean room table).
- 4.1.7 Cut from a coil a piece of 0.040"ID x .070" Microbore Tygon [P/N 200064-04] using a sharp #10 scalpel blade into square-ended, 12.93" (± 0.25 ") lengths as shown in FIGURE 5. (Refer to NeoMedix P/N 100068 drawing).

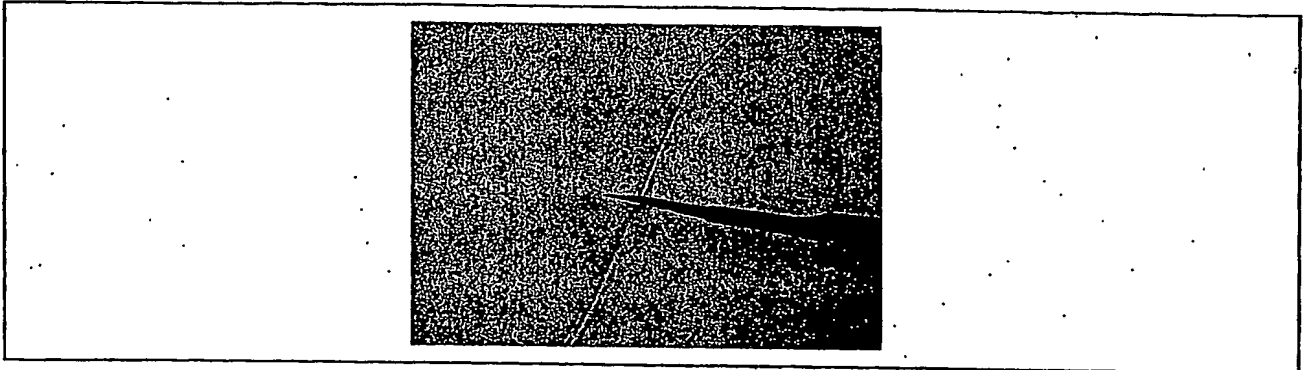


FIGURE 5. Cutting 0.040"ID x .070" Microbore Tygon

- 4.1.8 Apply and evenly distribute 2-drops of Loctite 3301 UV Adhesive [P/N 200005] using a 27G SS dispensing tip with a 1-second dispense cycle at 15psi around the outer circumference of one end of the cut-to-length 0.040"ID x .070"OD (hereafter referred to as "Aspiration Tubing Pigtail") approximately 0.050" back from the end of the tubing as shown in FIGURE 6.

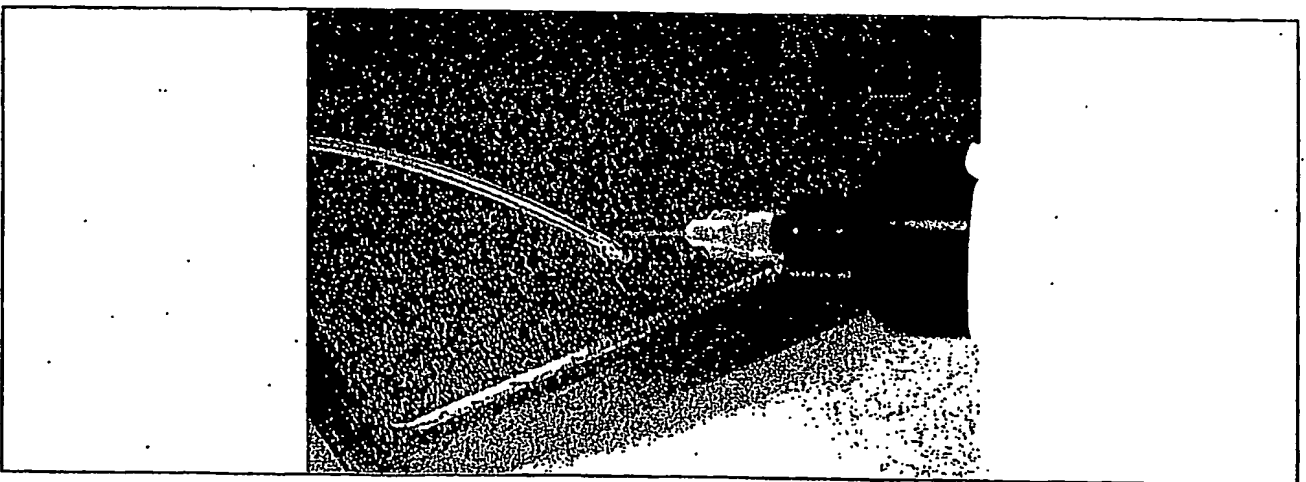


FIGURE 6. Applying Adhesive to Aspiration Tubing Pigtail

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- 4.1.9 Fully insert the adhesive coated end of the Aspiration Tubing Pigtail into the inner bore diameter of the Male Luer Lock Fitting [P/N 200062] as shown in FIGURE 7.

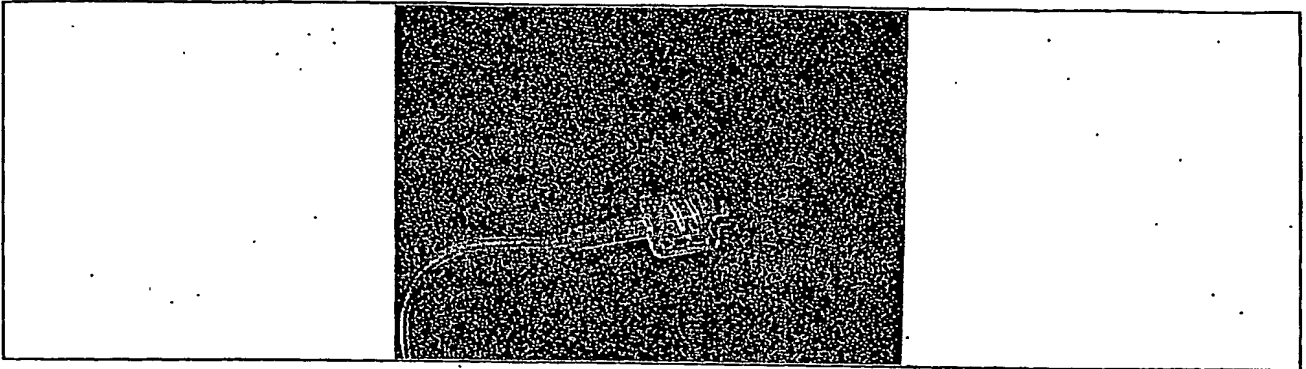


FIGURE 7. Bonding Aspiration Tubing Pigtail to Male Luer Fitting

- 4.1.10 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the tip of a single light guide positioned approximately 3" from the bond site.

4.2 BOND IRRIGATION TUBING PIGTAIL TO IRRIGATION TUBE ASSEMBLY

- 4.2.1 Place an Irrigation Tube Assembly [P/N 500018] into the Irrigation Sheath Holder [P/N 300030] with the smaller tapered end downward as shown in FIGURE 8. (Note: The Irrigation Sheath Holder can be completely loaded with subassemblies as an initial step if desired for expediency.)

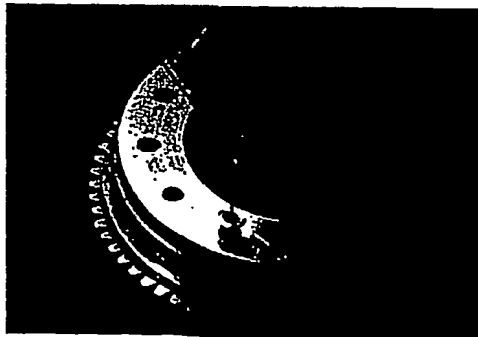


FIGURE 8. Placing Irrigation Sheath Subassy Into Holder

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- 4.2.2 Bottom out the distal end of the Irrigation Tubing Pigtail into the counterbore of the Irrigation Sheath Subassy as shown in **FIGURE 9**. (Note: The tubing should remain in place on its own after bottoming out from friction of the interference fit condition.)

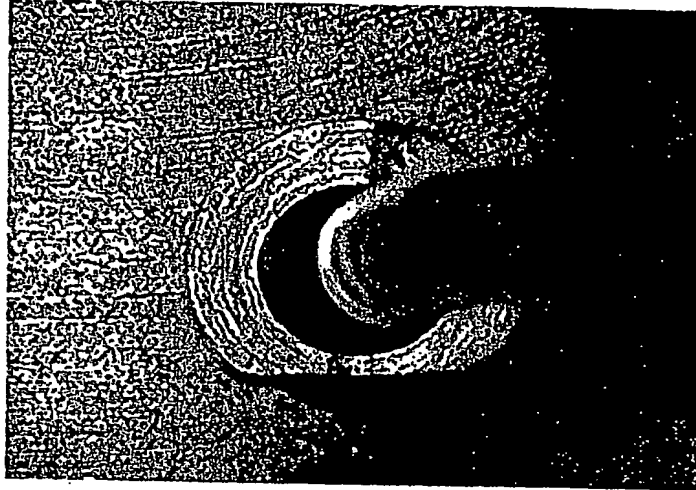


FIGURE 9: Placing Irrigation Tubing Into Counterbore

- 4.2.3 Apply Flashcure 4304 Adhesive [P/N 200068] to the bond site with a 30G dispensing tip making sure not to allow the adhesive to extend outside of the countersink feature at the proximal end of the Irrigation Sheath Subassy's counterbore as shown in **FIGURE 10**.

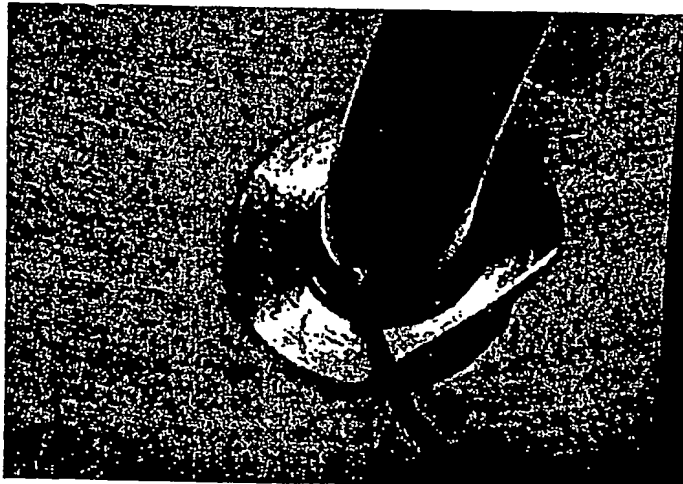


FIGURE 9. Bonding Irrigation Tubing Pigtail Into Counterbore

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- 4.2.4 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the tip of a single light guide positioned approximately 3" from the bond site.

4.3 BOND ASPIRATION TUBE TO IRRIGATION SHEATH SUBASSY

- 4.3.1 Position the Irrigation Sheath Subassy with its D-flat feature pointing upwards and carefully insert a 19G sharp needle through 1-wall only at a shallow angle to the tubing axis through an insertion point approximately 0.15" behind the D-flat flange and aligned rotationally closest to the D-flat. (See FIGURE 11.) Leave needle in place.

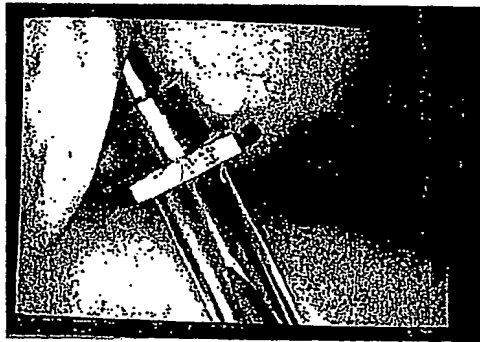


FIGURE 11. Inserting 19G Needle Into Tubing

- 4.3.2 Insert the blunt proximal end (end opposite the bent "Foot") of the Aspiration Tube [P/N 100061-06] into the inner bore of the small diameter end with the cross hole of the Irrigation Sheath Subassy as shown in FIGURE 12. Advance the Aspiration Tube and pass it completely through the inner diameter of the 19G needle until it exits the needle hub. Remove the 19G sharp needle leaving the Aspiration Tube emerging through the side opening of the Irrigation Tube pigtail.

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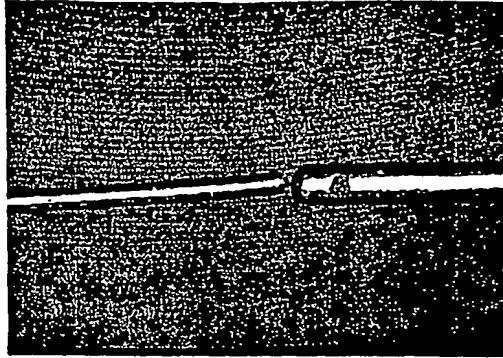


FIGURE 12. Inserting Aspiration Tube Into Irrigation Sheath Subassy

- 4.3.3 Insert the distal, 180° notch cutout of the Aspiration Tube into the notch of the fixture's "Rotational Key Pin" as shown in **FIGURE 13**.

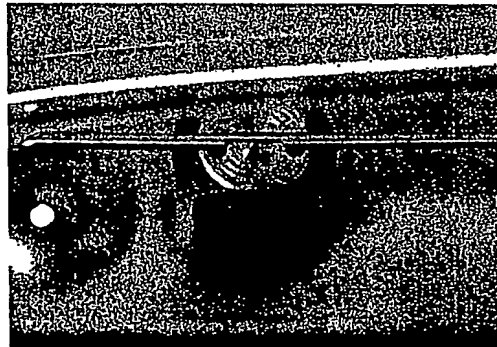


FIGURE 13. Orientation of Aspiration Tube Notch in Fixture

- 4.3.4 Push the D-shaped flange of the Irrigation Sheath Billet against the fixture stop as shown in **FIGURE 14**.

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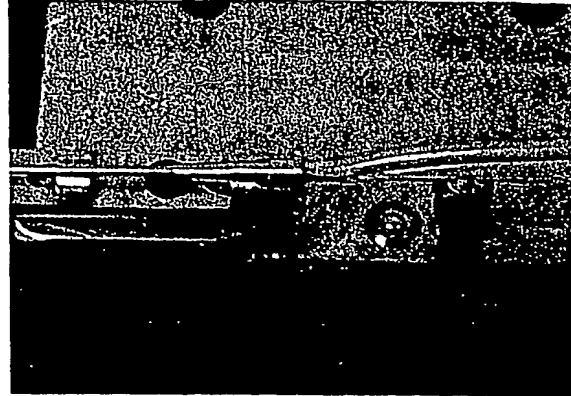


FIGURE 14. Positioning of Irrigation Sheath Billet in Fixture

- 4.3.5 Apply 1-drop of Flashcure 4305 Adhesive [P/N 200077] from a 23G x 1/2" SS dispensing tip to the location where the Aspiration Tube exits the Irrigation Sheath Subassy as shown in FIGURE 15.

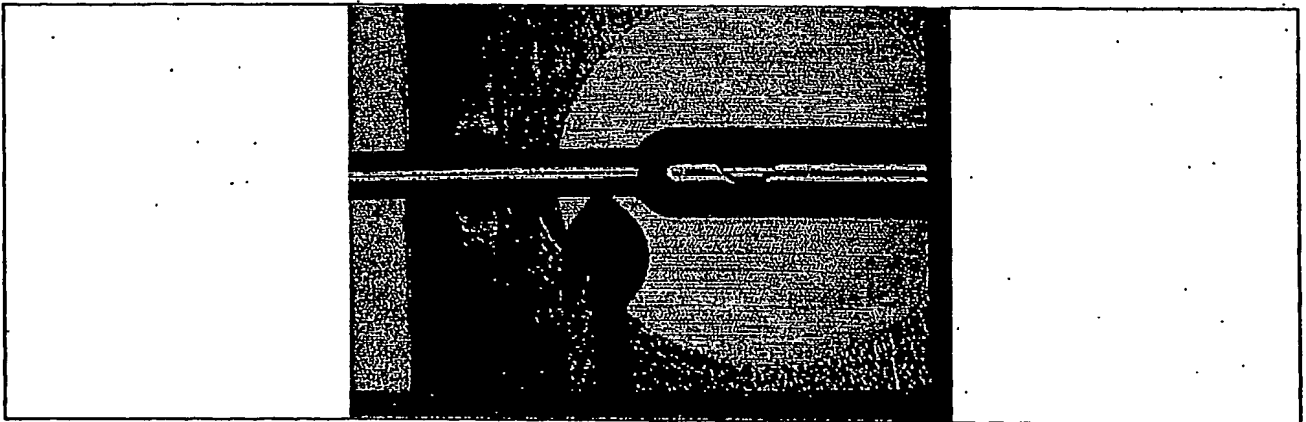


FIGURE 15. Applying Adhesive to Aspiration Tube Bond Site

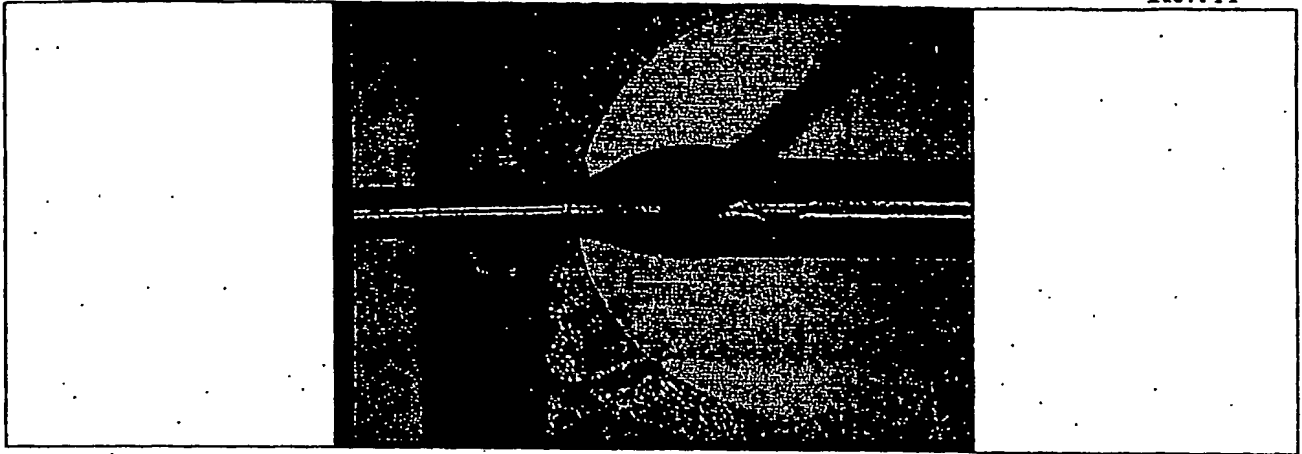
- 4.3.6 Use the dispensing tip to evenly distribute the dispensed adhesive drop around the circumference of the bond joint location paying special attention to the non-viewable side of the joint closest to the base of the fixture as shown in FIGURE 16.

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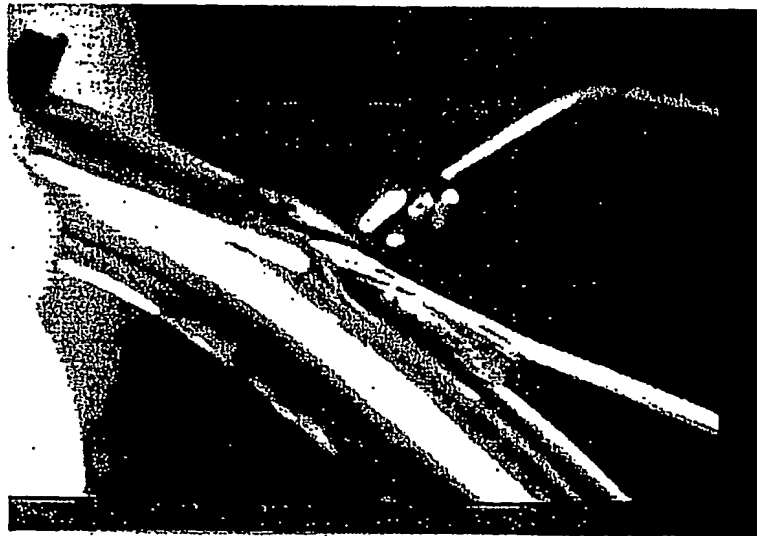
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**FIGURE 16. Distributing Adhesive Drop Around Tube Circumference**

- 4.3.7 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the tip of a single light guide positioned approximately 3" from the bond site.
- 4.3.8 Apply and evenly distribute 2-drops of Flashcure 4305 Adhesive [P/N 200077] using a 23G x 1/2" SS dispensing tip to the 19G needle pierce location where the Aspiration Tube exits the inner diameter of the Irrigation Tubing Pigtail and cure immediately with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power. (See **FIGURE 17.**)

**FIGURE 17. Sealing the 19G Needle Pierce Location****Confidential****CONTROL DOCUMENT**

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4.4 PIERCING THE ASPIRATION TUBING WITH NEEDLE INTRODUCER

- 4.4.1 Carefully grasp the square-cut end of the Aspiration Tubing Pigtail between the thumb and forefinger of one hand and insert a 19G sharp needle through 1-wall only at a shallow angle to the tubing axis through an insertion point approximately 0.170" from the end until the needle tip extends past the cut end of the tubing. (See FIGURES 18a and 18b.)

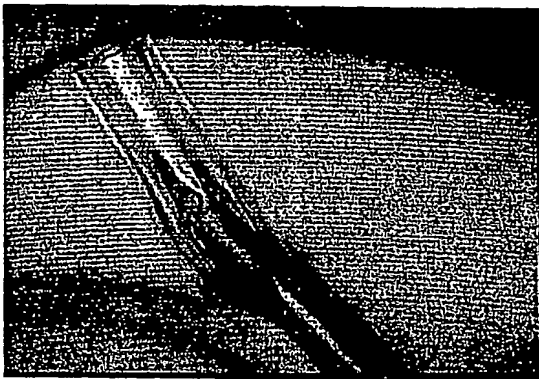


FIGURE 18a. Grasping and Insertion Method

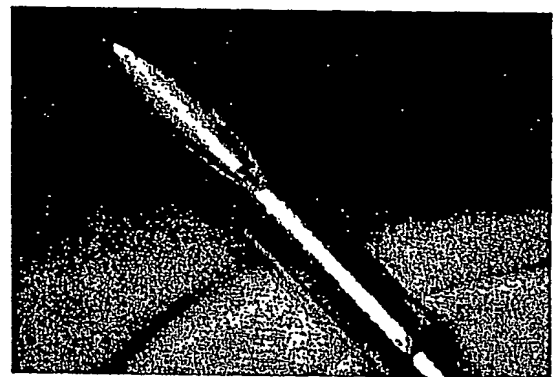


FIGURE 18b. Final Needle Insertion Position

4.5 POSITIONING AND BONDING ASPIRATION TUBING PIGTAIL

- 4.5.1 Hold the proximal end of the Aspiration Tube between the thumb and forefinger of one hand and insert its proximal (gold-plated) end into the inner bore of the 19G needle tip as shown in FIGURE 19.

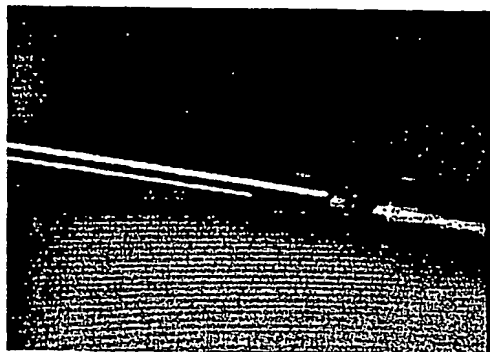


FIGURE 19. Inserting Aspiration Tube End Into 19G Needle

- 4.5.2 Advance the Aspiration Tubing Pigtail with the inserted 19G needle until the end of the tubing extends approximately 0.050" beyond the distal notch of the

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Aspiration Tube as shown in **FIGURE 20**. (Note: Advance the 19G needle smoothly and aligned with the axis of the Aspiration Tube to prevent abrasion of the metal surface and the gold plating.)

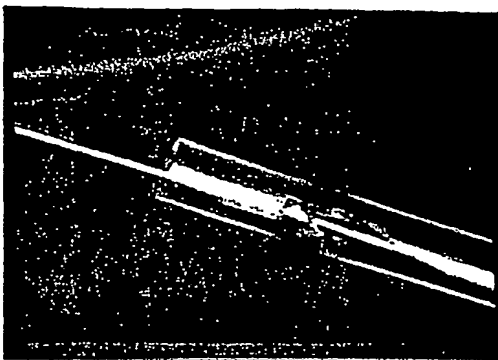


FIGURE 20. Positioning of Aspiration Tubing End vs. Tube Notch

- 4.5.3 Hold the Aspiration Tubing Pigtail in a fixed axial position by pinching the Aspiration Tubing radially inwards against the Aspiration Tube with Insulated Foot between the thumb and forefinger of one hand and carefully retract the 19G needle out of the tubing lumen's pierce site and off the end of the Aspiration Tube as shown in **FIGURES 21a** and **21b**. (Note: Place a cap or other protective means over the sharp tip of the 19G needle when not in use.)

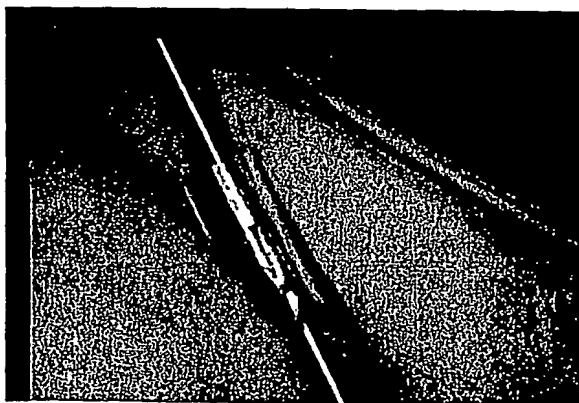


FIGURE 21a. Grasping and Extraction Method

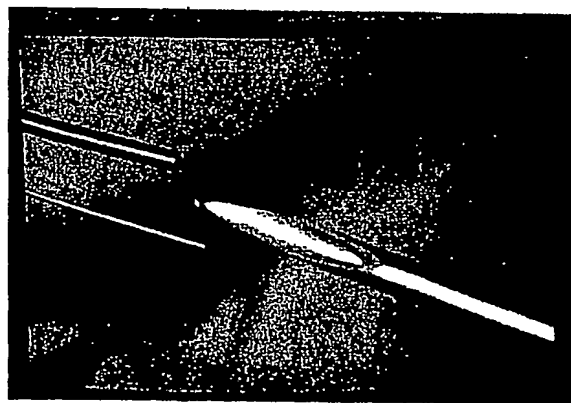


FIGURE 21b. Final Needle Extraction Position

- 4.5.4 While maintaining the ~0.050" axial overlap distance between the end of the tubing and the distal notch edge, orient the subassembly such it is parallel to the assembly surface with the D-flat feature facing upwards and allow the

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Aspiration Tubing Pigtail to exit downwards and ~30° counterclockwise (when viewed from the tubing side) as shown in **FIGURE 22**.

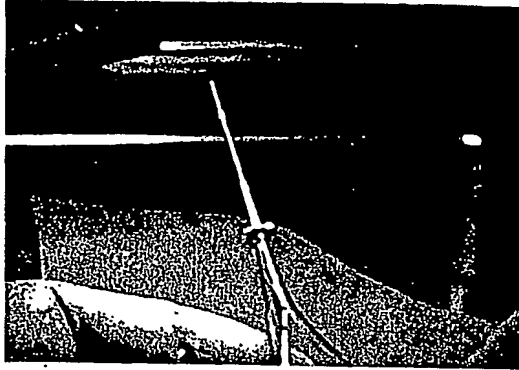


FIGURE 22. Rotational Alignment of Aspiration Tubing Pigtail

- 4.5.5 Apply 1-drop of Flashcure 4305 Adhesive [P/N 200077] using a 23G x ½" SS dispensing tip to the open end of the Aspiration Tubing Pigtail (see **FIGURE 23**.) and cure immediately with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power. (Note: Adhesive must completely seal around the circumference of the Aspiration Tubing Pigtail end as must be cured rapidly to prevent adhesive from wicking into and occluding the notch opening.)

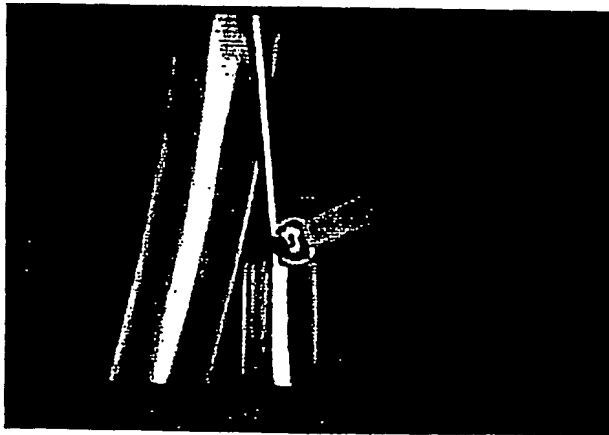


FIGURE 23. Sealing Distal End of Aspiration Tubing

- 4.5.6 Apply 1-drop of Flashcure 4305 Adhesive [P/N 200077] using a 23G x ½" SS dispensing tip to the pierce site where Aspiration Tube exits through the side wall of the Aspiration Tubing Pigtail (see **FIGURE 24**.) and cure immediately with a 6-second minimum cycle of the Lesco SuperSpot Max

NEOMEDIX Corporation

Title: MI - Inner Unsupported Subassy

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UV Cure System set to minimum power. (Note: Adhesive must completely cover and seal the pierce site which may be elongated due to variability in the needle insertion and must be cured rapidly to prevent adhesive from wicking into and occluding the inner diameter of the tubing.)

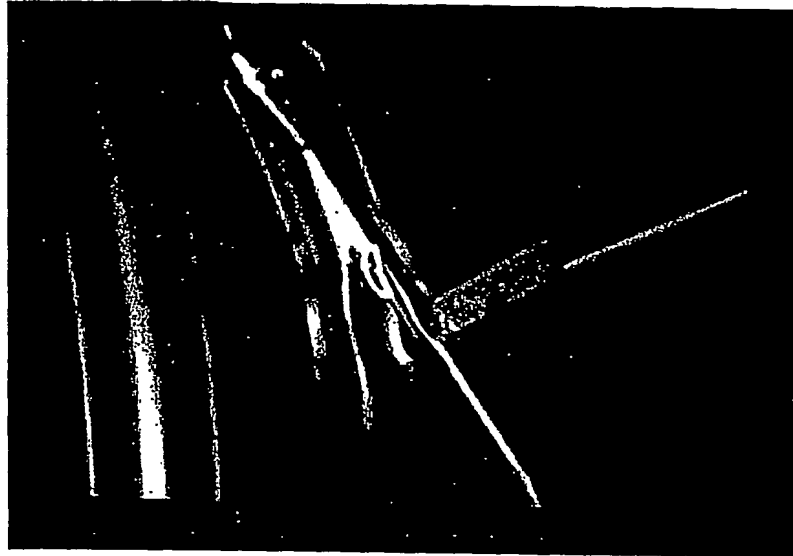


FIGURE 24. Sealing Needle Pierce Site of Aspiration Tubing Pigtail

4.6 POSITIONING AND BONDING THE TITANIUM ELECTRODE WIRE

- 4.6.1 Bend the Aspiration Tube to an approximate angle of 45° at the tube's middle notch as shown in FIGURE 25.

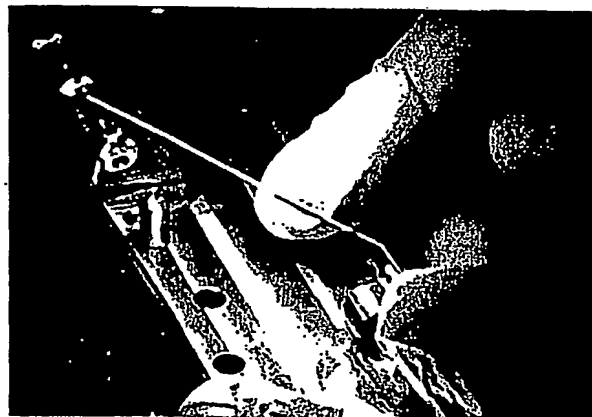


FIGURE 25. Bending Aspiration Tube at Notch

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Rev. A

- 4.6.2 Insert the Polyimide coated end of the Titanium Electrode Wire [P/N 100087] into the inner diameter of the Aspiration Tube at the middle bent notch location as shown in **FIGURE 26**.

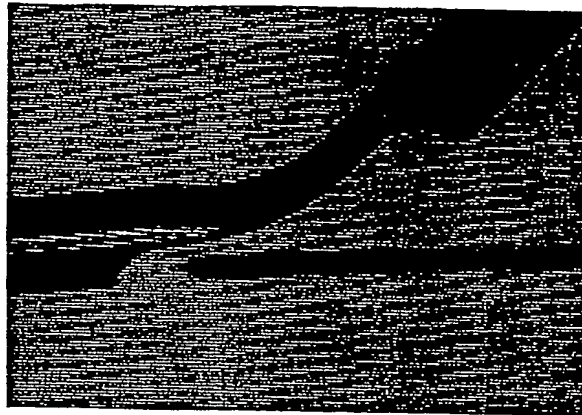


FIGURE 26. Insertion Location for Titanium Electrode Wire

- 4.6.3 Advance the Titanium Electrode Wire until its distal Polyimide coated end passes through the inside cutout of the Aspiration Tube's "Return Tab" as shown in **FIGURE 27**. (Note: Slight downward pressure on the rear end of the wire combined with rotation may help the tip of the wire align with and pass through the internal cutout, otherwise the "Return Tab" may need to be further flexed radially inward.)



FIGURE 27. Passing Electrode Wire Thru "Return Tab" Cutout

- 4.6.4 Position the distal Titanium Electrode Wire end flush with the small flat distal tip of the "Return Tab" as shown in **FIGURE 28**.

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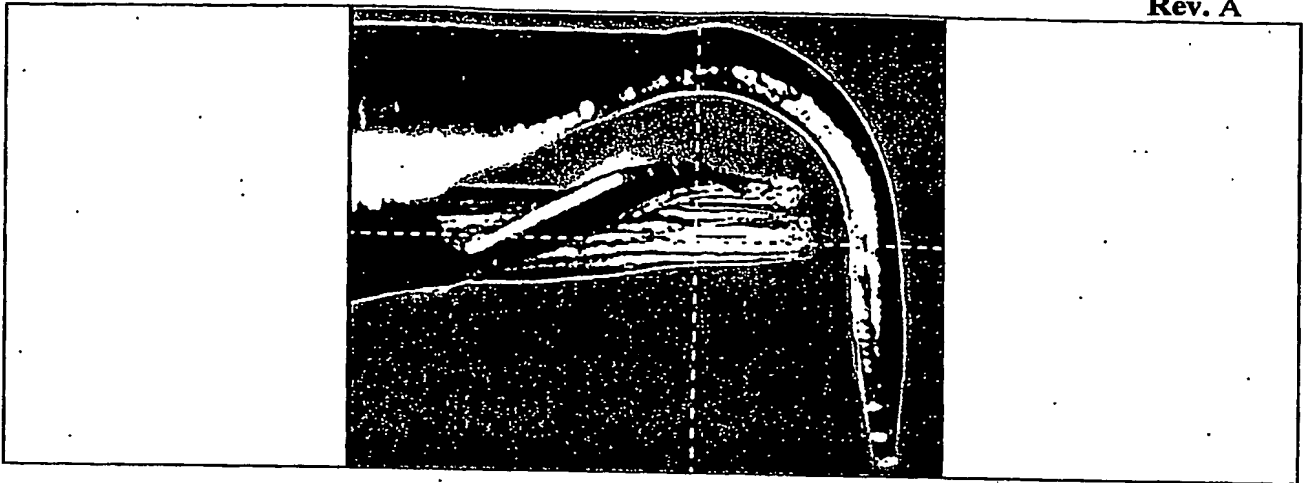


FIGURE 28. Final Positioning of Electrode Wire To "Return Tab"

- 4.6.5 Bond Titanium Electrode Wire to the Aspiration Tube with a minimal amount of Flashcure 4305 Adhesive [P/N 200077] applied to the proximal edge of the "Return Tab's" internal cutout using a 32G dispensing tip as shown in FIGURE 29. (Note: It may be necessary to clean and replace tips often.)

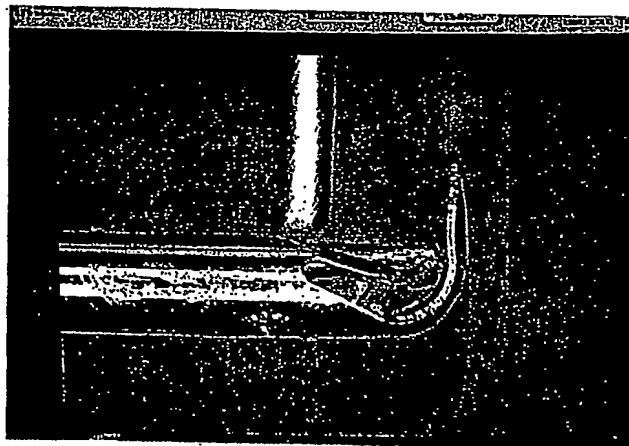


FIGURE 29. Bonding Insulated Electrode Wire to "Return Tab"

- 4.6.6 Cure adhesive with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power with the tip of a single light guide positioned approximately 3" from the bond site.
- 4.6.7 Apply 1-drop of Flashcure 4305 Adhesive [P/N 200077] using a 23G x 1/2" SS dispensing tip to the notch location where the Titanium Electrode Wire

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exits the inner diameter of the tube and cure immediately with a 6-second minimum cycle of the Lesco SuperSpot Max UV Cure System set to minimum power. (See FIGURE 30.)

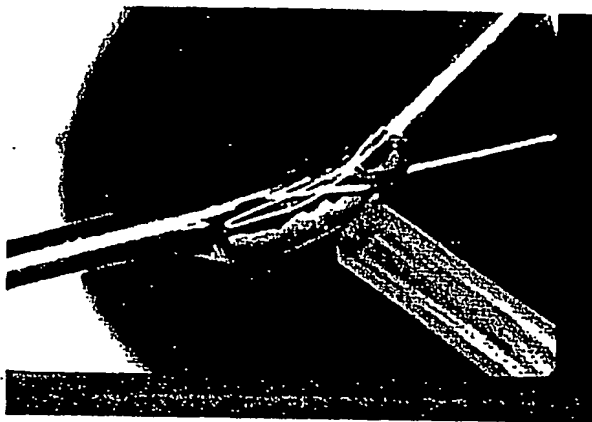
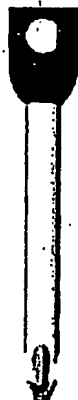


FIGURE 30. Sealing of Aspiration Tube Proximal Site

- 4.6.8 Apply additional single drop increments of Flashcure 4305 Adhesive and cure immediately until the inner diameter of Aspiration Tube extending towards the distal tip is completed sealed closed. (Note: The sealed condition will be indicated when adhesive will no longer wick inside the Aspiration Tube when applied.)

4.7 INSPECTING SUBASSEMBLY

- 4.7.1 Verify that the "Foot" feature at the distal tip of the Aspiration Tube is rotationally aligned within 20° of the axis of the irrigation outflow holes in the Irrigation Tube Assembly as shown in FIGURE 31. ("REJECT" any assemblies that do not conform to this requirement.)



NEOMEDIX Corporation

Title: MI - Inner Unsupported Subassy

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Rev. A

FIGURE 31. Alignment of "Foot" with Irrigation Outflow Holes

- 4.7.2 Verify that the "Foot" feature has not been damaged or deformed during the handling of the assembly. ("REJECT" any assemblies that have damaged or deformed features.)
- 4.7.3 Verify that there is no adhesive residue that has been deposited on the distal tip of the "Return Tab". ("REJECT" any assemblies that have cured adhesive outside of specified bond regions.)
- 4.7.4 Verify visually that the Irrigation Tubing Pigtail pierce site (see FIGURE 17) has been completely sealed with adhesive and that there is no adhesive buildup extending more than 0.040" radially from the OD of the Irrigation Tubing. ("REJECT" any assemblies that do not conform to these requirements if a single additional adhesive dispense and cure cycle per Step 4.3.8 does not create an adequate sealing joint.)
- 4.7.5 Verify visually that the Aspiration Tubing Pigtail bond sites (see FIGURES 23 and 24) have been completely sealed with adhesive, that the notch in the Aspiration Tube is not occluded, and that there is no adhesive buildup extending more than 0.040" radially from the OD of the Aspiration Tubing. ("REJECT" any assemblies that do not conform to these requirements if a single additional adhesive dispense and cure cycle per Step 4.5.6. does not create an adequate sealing joint.)
- 4.7.6 Place all "Accepted" assemblies tip downward into a suitable protective holder means (protects the assemblies from damage and collection of debris) labeled with NeoMedix P/N, WO#, quantity, and date.
- 4.7.7 Place all "REJECTED" assemblies in clean bins labeled with "REJECTED", NeoMedix P/N, WO#, quantity, and date. ("REJECTED" assemblies should be placed in a designated QC Quarantine area for later review.)
- 4.7.8 Count the total number of "ACCEPTED" and "REJECTED" subassemblies, record the data on the Work Order, and return all documents to the Completed Work Order File.

NEOMEDIX
Corporation

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Manufacturing Instructions

MI 400033

Title: MI - I/A Tube Set Subassy

Rev. A

Prepared By: James Gerg

Release Level: Clinical

ECN No:

Release Approved By:

Date:

417-03

J. Loewen

05/05/03

1.0 PURPOSE

Details the steps required to assemble the I/A Tube Set Subassy for personnel experienced in assembling disposable medical devices.

2.0 TOOLS AND SUPPLIES

- Scalpel blade holder (or equivalent)
- #10 scalpel blade (or equivalent)
- Clean Scissors (or equivalent for cutting Cohesive Tape)
- Lint-free cloth (or equivalent)
- 70% Isopropanol (NeoMedix P/N 200110 or equivalent)
- Non-powdered gloves (UVPS- NT Surgical Type or equivalent)

3.0 MATERIALS

All materials are listed in the assembly drawing NeoMedix P/N 500033.

Additional referenced documents: N/A

NEOMEDIX Corporation

Title: MI - I/A Tube Set Subassy

MI 400033

Rev. A

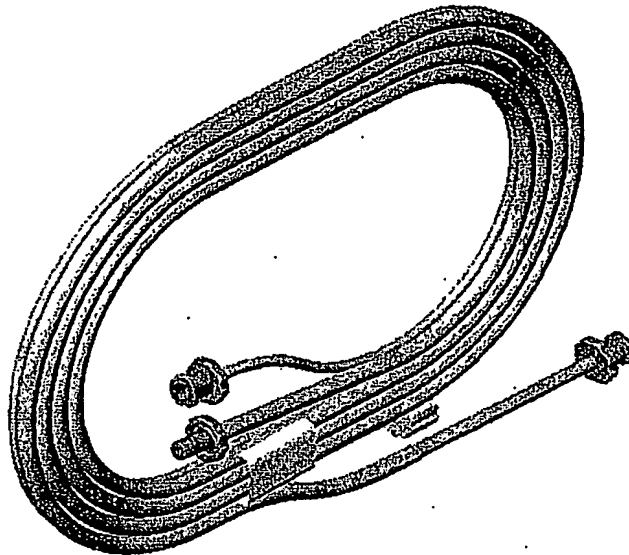
4.0 PROCEDURE

FIGURE 1. Finished Subassembly

4.1 ISOPROPANOL WIPEDOWN OF PARATUBE

- 4.1.1 Wear gloves at all times and work under a laminar flow hood for all steps.
- 4.1.2 Moisten a lint-free cloth with 70% Isopropanol [NeoMedix P/N 200110].
- 4.1.3 Wipe the outside surfaces of the I/A Extension Paratube [NeoMedix P/N 100085] along its entire length. (Note: Inspect the lint-free cloth for debris often and replace as necessary. Re-apply Isopropanol to the lint-free cloth frequently.)
- 4.1.4 Allow the Isopropanol to fully evaporate from the outside surfaces of the I/A Extension Paratube lengths. (Note: There should never be any Isopropanol inside the lumens.)
- 4.1.5 Place cleaned I/A Extension Paratube lengths into clean bins and place in cleanroom pass through window.

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4.2 SPLITTING PARATUBE ON ONE END AND INSERTING FITTINGS

- 4.2.1 Split the paratube lumens apart on one end only using gloved finger pressure to a distance of 2.0" (+/- 0.4") as shown in FIGURE 2.

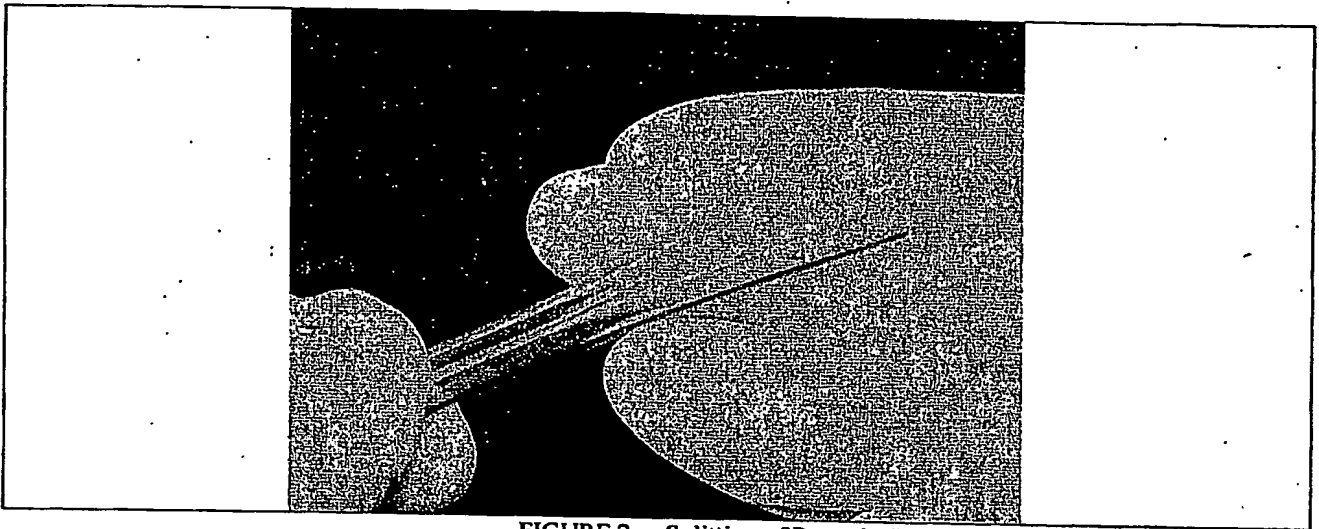


FIGURE 2. Splitting of Paratube Lumens

- 4.2.2 Insert the 1/16" Barbed Female Luer Fitting [P/N 200085] into the smaller (non-striped) lumen of the split paratube until the tubing end bottoms out against the fitting's flange as shown in FIGURE 3.

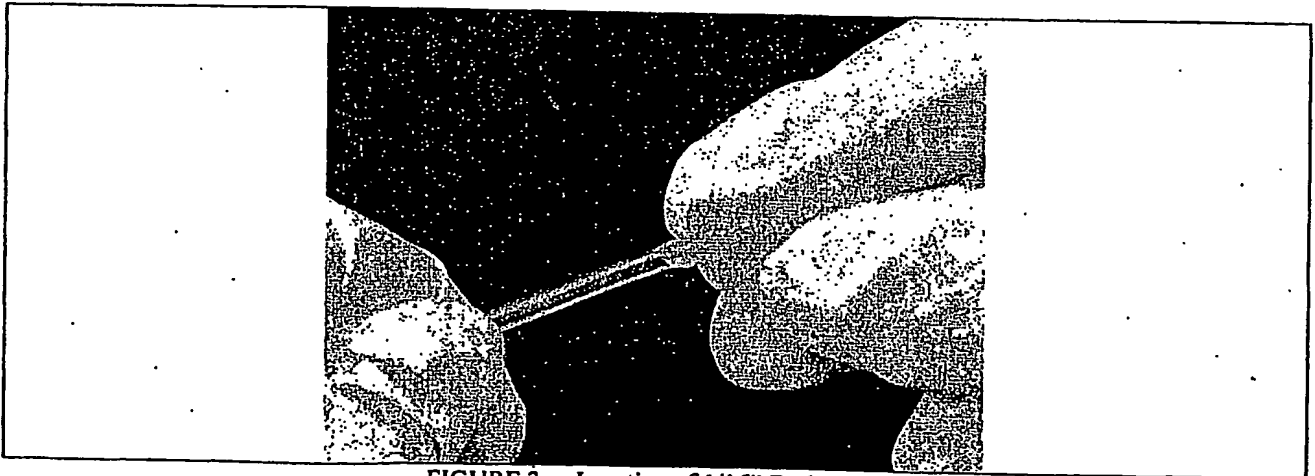


FIGURE 3. Insertion of 1/16" Barbed Female Luer Fitting into Smaller Lumen

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- 4.2.3 Insert the 3/32" Barbed Male Slip Luer Fitting [P/N 200112] into the larger (green-striped) lumen of the split paratube until the tubing end bottoms out against the fitting's flange as shown in FIGURE 4. (Note: Do not twist fitting while inserting because it will cosmetically distort the green-striped lumen in the stretched barb region.)

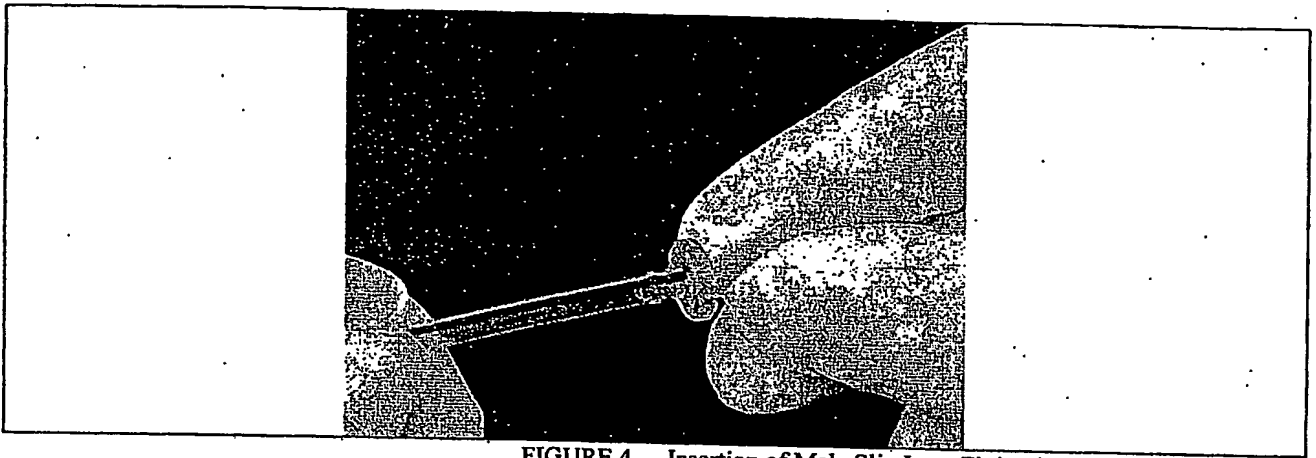


FIGURE 4. Insertion of Male Slip Luer Fitting into Larger Lumen

4.3 SPLITTING OTHER PARATUBE END AND INSERTING FITTINGS

- 4.3.1 Split the remaining paratube lumen ends apart using gloved finger pressure to a distance of 4.0" (+/- 0.5") as shown in FIGURE 5.

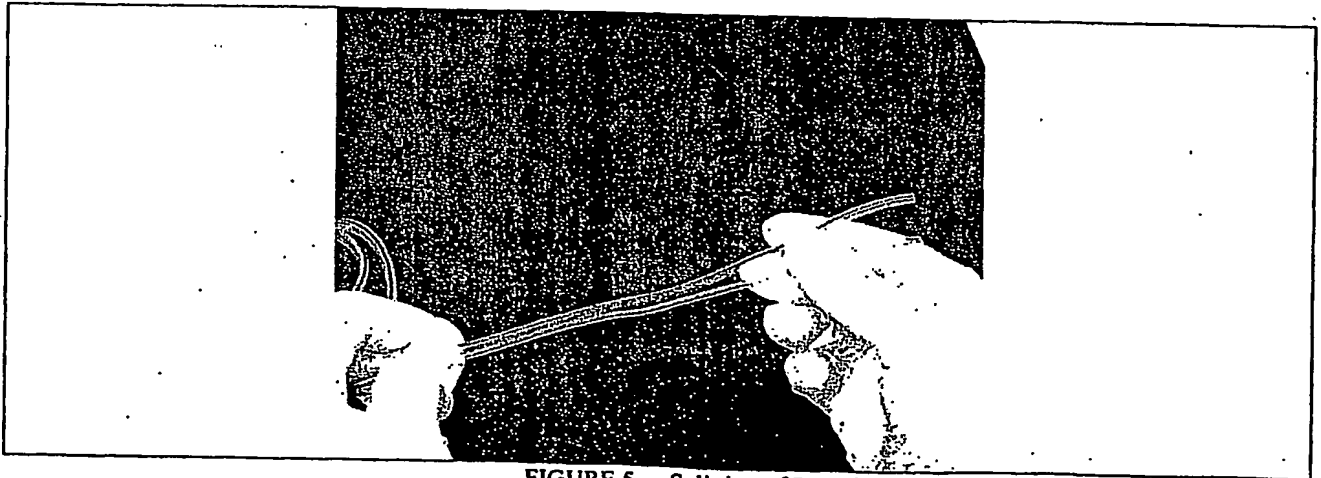


FIGURE 5. Splitting of Remaining Paratube Lumen Ends

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Title: MI - I/A Tube Set Subassy

MI 400033

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- 4.3.2 Insert the 1/16" Barbed Male Luer Lock Fitting [P/N 200079] into the smaller (non-striped) lumen of the split paratube until the tubing end bottoms out against the fitting's flange as shown in FIGURE 6.

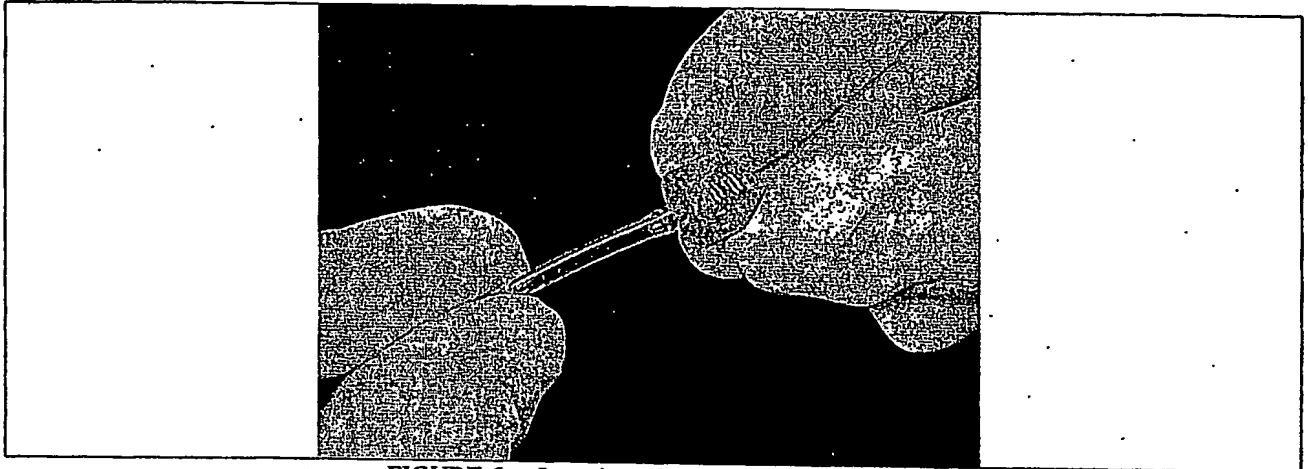


FIGURE 6. Insertion of 1/16" Barbed Male Luer Lock Fitting into Smaller Lumen

- 4.3.3 Insert the 3/32" to 3/32" Barb Fitting [P/N 200111] into the larger (green-striped) lumen of the split paratube until the tubing end bottoms out against the fitting's flange as shown in FIGURE 7. (Note: Do not twist fitting while inserting because it will cosmetically distort the green-striped lumen in the stretched barb region.)

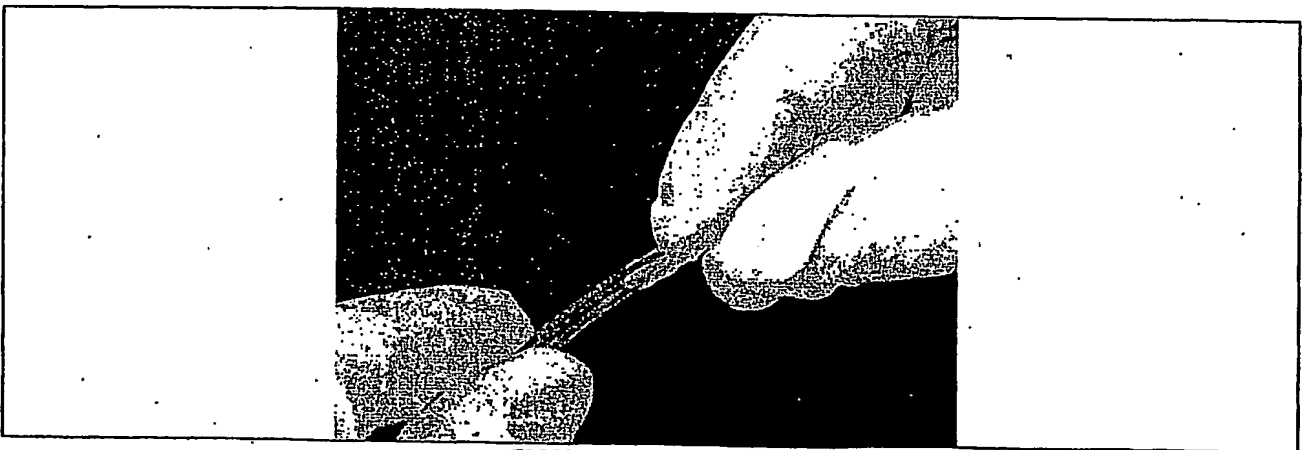


FIGURE 7. Insertion of 3/32" to 3/32" Barb Fitting into Larger Lumen

NEOMEDIX Corporation

Title: MI - I/A Tube Set Subassy

MI 400033

Rev. A

4.4 CUTTING SILICONE TUBING TO LENGTH AND INSERTING FITTINGS

- 4.4.1 Cut Platinum-Cured Silicone Tubing (0.078"ID/0.125"OD) [P/N 200103-09] to a length of 2.0" (+/-0.3") using a sharp #10 scalpel blade ensuring that the ends are cut square. (Note: Do not cut the tubing while in a stretched condition in order to allow for the best cut length repeatability.)
- 4.4.2 Insert the 3/32" Barbed Female Luer Fitting [P/N 200109] into one end of the cut silicone tubing length until the tubing end bottoms out against the fitting's flange as shown in FIGURE 8. (Note: Ensure that the tubing axis is aligned (not crooked) to the axis of the barb. Twist and or push/pull the tubing until it is coaxial with the barb fitting.)

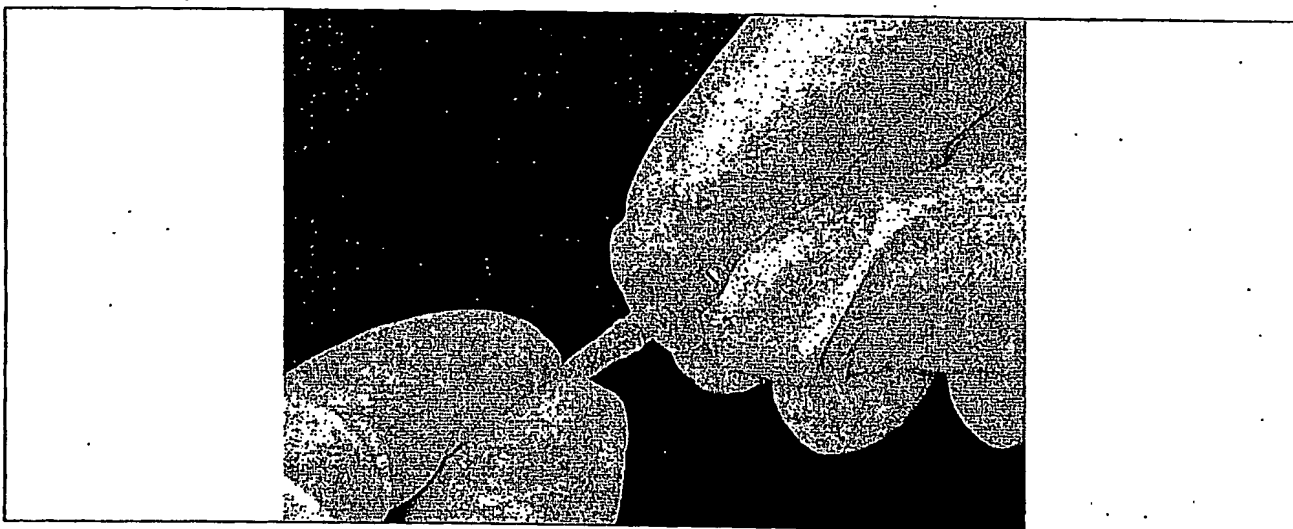


FIGURE 8. Insertion of 3/32" Barbed Female Luer Fitting into Silicone Tube

- 4.4.3 Insert the remaining open end of the cut silicone tubing over the barb of the 3/32" to 3/32" Barb Fitting (it's other end is already inserted into the large (green-striped) paratube lumen) until the tubing end bottoms out against the fitting's flange as shown in FIGURE 9. (Note: Ensure that the tubing axis is aligned (not crooked) to the axis of the barb. Twist and or push/pull the tubing until it is coaxial with the barb fitting.)

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Title: MI - I/A Tube Set Subassy

MI 400033

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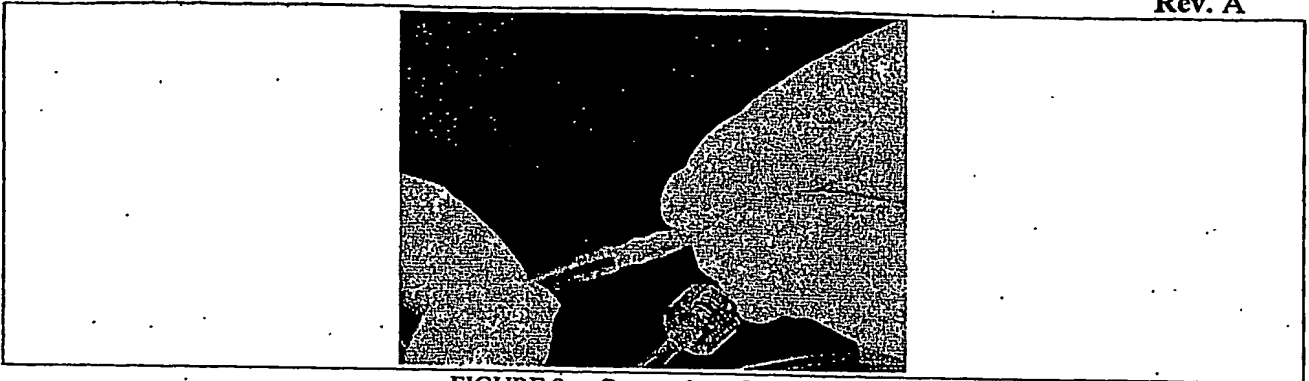


FIGURE 9. Connection of Silicone Tubing length to 3/32" to 3/32" Barb Fitting of Large (Green-striped) Paratube Lumen

4.5 COILING OF TUBE SET AND SECURING WITH COHESIVE TAPE

- 4.5.1 Cut Cohesive Tape [P/N 200065] to a length of 2.5" (+1.0"/-0.5") using clean scissors.
- 4.5.2 Coil the assembled tube set around a form to a diameter of 5.2."
- 4.5.3 Remove the coiled tube set from the form and secure into a tight shape, as shown in FIGURE 10, with the cut Cohesive Tape strips. (Note: The folded-over Cohesive Tape sections should be aligned width-wise and should be placed as shown in FIGURE 10 midway between the 2 sets of opposite-facing paratube fittings.)

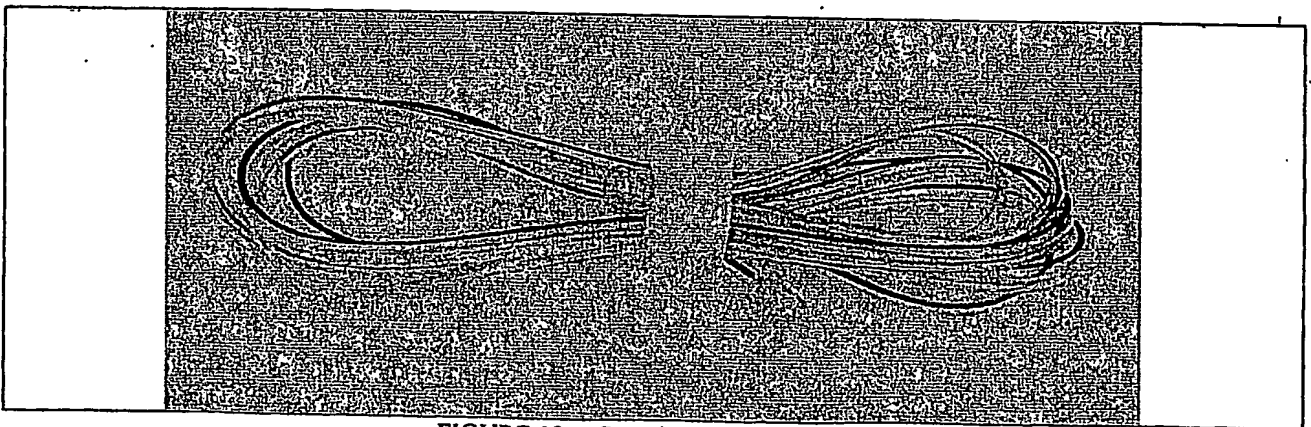


FIGURE 10. Securing of Coiled Tube Set in "Figure-8" With Cohesive Tape.

- 4.5.4 Trim the ends of the Cohesive Tape to be neat and even.

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Title: MI - I/A Tube Set Subassy

MI 400033

Rev. A

4.6 INSPECTING SUBASSEMBLIES

- 4.6.1 Verify that all fittings are coaxial with the tubing lumens and are fully bottomed-out into the tubing ends. (Readjust if necessary)
- 4.6.2 Verify that the tubing is not kinked and is well secured with Cohesive Tape. (Remove and reapply Cohesive Tape if necessary.)
- 4.6.3 Place all visually "ACCEPTED" coiled tube set assemblies into clean bins and label with Assy P/N, WO #, quantity, and date.
- 4.6.4 Mark all packages of unused and unopened items as "Return to Inventory".
- 4.6.5 Mark all packages of parts not used due to defects with "Defective Parts" along with the WO#, quantity, and any pertinent description. ("Defective Parts" should either be discarded or reviewed if possible by Mfg/QC Engineering.)
- 4.6.6 Verify the total number of "ACCEPTED" and "REJECTED" tube set assemblies, record the data on the Work Order, and return all documents to the Completed Work Order File.

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Corporation**

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60477258.061003

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Manufacturing Instructions

MI 450001

Title: MI - Irrigation Set Pouched

Rev. A

Prepared By: J. Elias

Release Level: Clinical

ECN No:

Release Approved By:

Date:

420-03

J. Lounser

04/24/03

1.0 PURPOSE

Details the steps required to assemble the Irrigation Set [P/N 550001], for personnel experienced in assembling disposable medical devices. The steps include labeling the pouch, packaging pouches and shipping to outside vendor for secondary operations.

2.0 TOOLS AND SUPPLIES

- Powder-free exam gloves or equivalent

3.0 MATERIALS

All materials are listed in the assembly drawing for NeoMedix P/N 550001.

Additional referenced documents: N/A

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NEOMEDIX Corporation

Title: MI - Irrigation Set Pouched

MI 450001

Rev. A

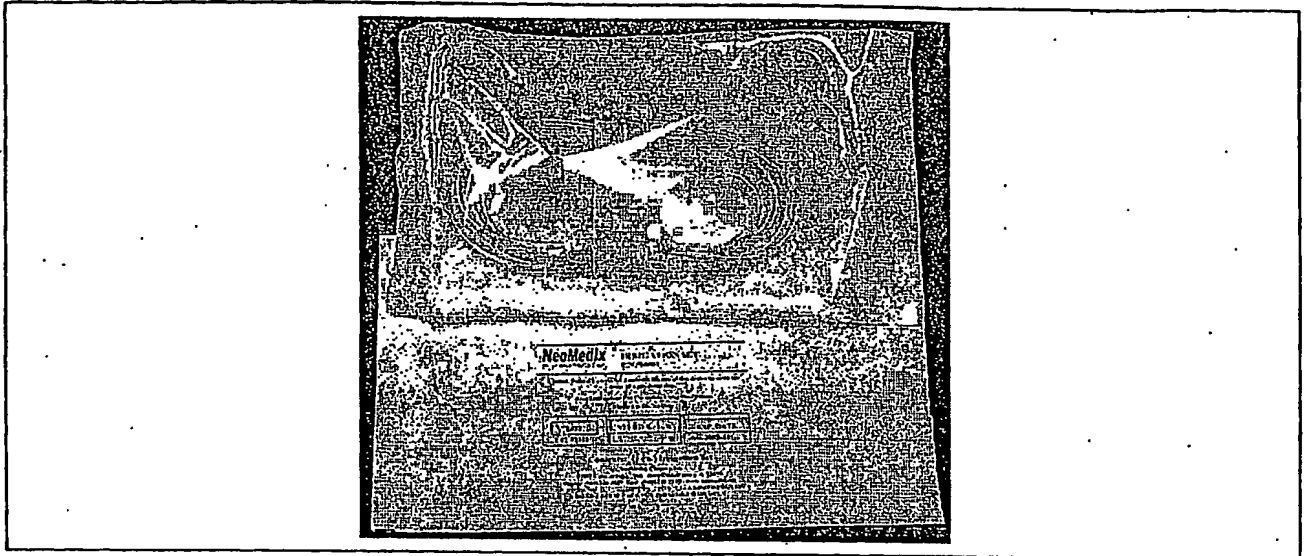


FIGURE 1. Completed 550001 Assembly

4.0 PROCEDURE**4.1 LABELING THE POUCH**

- 4.1.1 Apply Irrigation Set Label [P/N 190022] centered on the Tyvek (white) side of the Pouch [P/N 200066] in the orientation shown on the assembly drawing.
- 4.1.2 Place completed pouches in poly bag and seal bag with tape.
- 4.1.3 Place sealed bag in pass through window.

4.2 EAGLE LABORATORIES

- 4.2.1 Prepare shipping box for pouches to Eagle Laboratories.
- 4.2.2 Eagle will insert one Single Port I.V. Line [Eagle P/N 200-01] into one labeled irrigation pouch (NMX P/N 500016).
- 4.2.3 Seal the pouch using a pouch sealer.

4.3 STERILIZATION

- 4.3.1 Package the completed subassemblies into a shipping box for shipping to Gamma Sterilizer for sterilization.

NEOMEDIX Corporation

Title: MI - Irrigation Set Pouched

MI 450001

Rev. A

- 4.3.2 Gamma sterilize units at appropriate dosage. Include sterilization record with units.
- 4.3.3 Return units [NMX P/N 550001] to NeoMedix.

4.4 INVENTORY

- 4.4.1 Place the finished subassembly into appropriate labeled bins with the Work Order #, Assembly P/N, Lot Number, and Quantity.
- 4.4.2 Place sterilization record in document control for filing.

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Manufacturing Instructions

MI 450002

Title: MI – Pouched Aspiration Set

Rev. A

Prepared By: James Gerg

Release Level: Clinical

ECN No:
418-03

Release Approved By:

J. Lounan

Date:

04/24/03

1.0 PURPOSE

Details the steps required to assemble the Pouched Aspiration Set [P/N 550002], for personnel experienced in assembling disposable medical devices. The steps include cutting the pump tube length, inserting fittings into the pump tube, attaching the pump tube fitting to the collection bag, attaching a stopcock and syringe, labeling the pouch, and sealing the assembled components into the pouch.

2.0 TOOLS AND SUPPLIES

- Scalpel blade handle with #10 blades – (for cutting square ended tubing to length)
- Ruler or Caliper – (min. 6" tubing length measuring capability)
- UV protective gloves (UVPS- NT Surgical Type, non-powdered) or equivalent
- #1 Flat-bladed screwdriver or equivalent
- Impulse Pouch Sealer (American International Electric Model AIE-305AI) or equivalent

3.0 MATERIALS

All materials are listed in the assembly drawing for NeoMedix P/N 550002.

Additional referenced documents:

NMX 850006 Op. Instruction AIE-305AI Impulse AutoSealer

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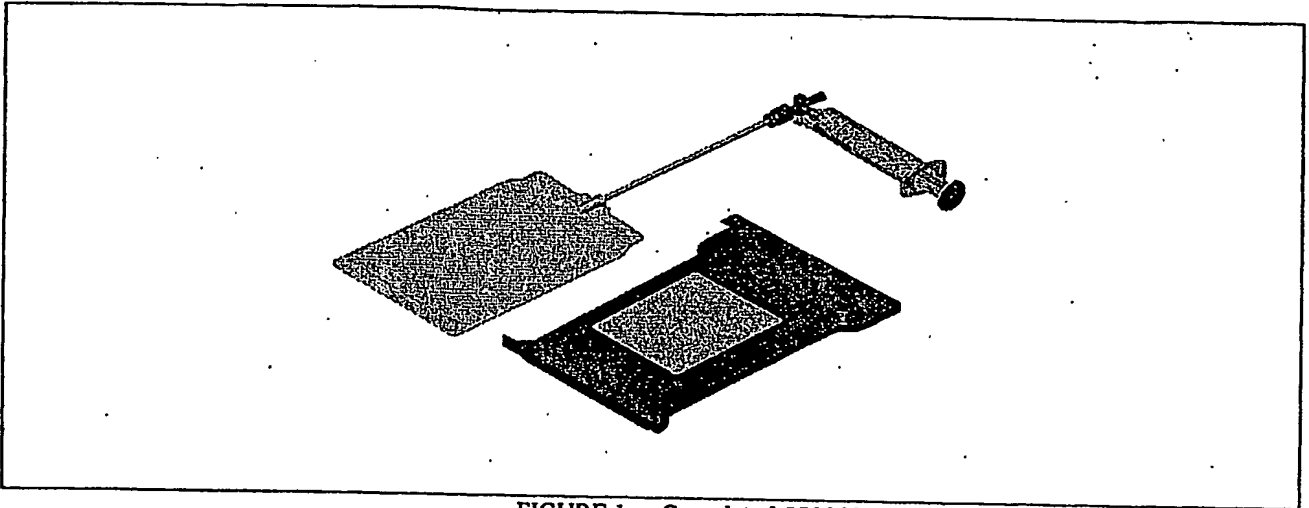


FIGURE 1. Completed 550002 Assembly

4.0 PROCEDURE

4.1 CUTTING THE PUMP TUBING

- 4.1.1 Wear gloves for all assembly steps.
- 4.1.2 Measure 6.0" and mark the 6.0" measurement on a table with tape. (This will be used for cutting the (Item 2) Silicone Pump Tubing [P/N 200070-01] to length.
- 4.1.3 Clean and label bins with the work order number and part number.
- 4.1.4 Extend the silicone pump tubing to the 6.0" mark and cut the Silicone Pump Tubing perpendicular to the table creating a square-ended tube.
- 4.1.5 Place the 6.0" lengths of tubing into the appropriately labeled bins.
- 4.1.6 Count number of cut tubes and record on the labeled bins.

4.2 INSERTING FITTINGS INTO THE CUT SILICONE PUMP TUBING ENDS

- 4.2.1 Wear gloves for all assembly steps.
- 4.2.2 Press the small barbed end of (Item5) 1/16" Barbed Female Luer Fitting [P/N 200085] fully into one end of the 6.0" long Silicone Pump Tubing lengths as shown in FIGURE 2.

NEOMEDIX Corporation

Title: MI - Pouched Aspiration Set

MI 450002

Rev. A

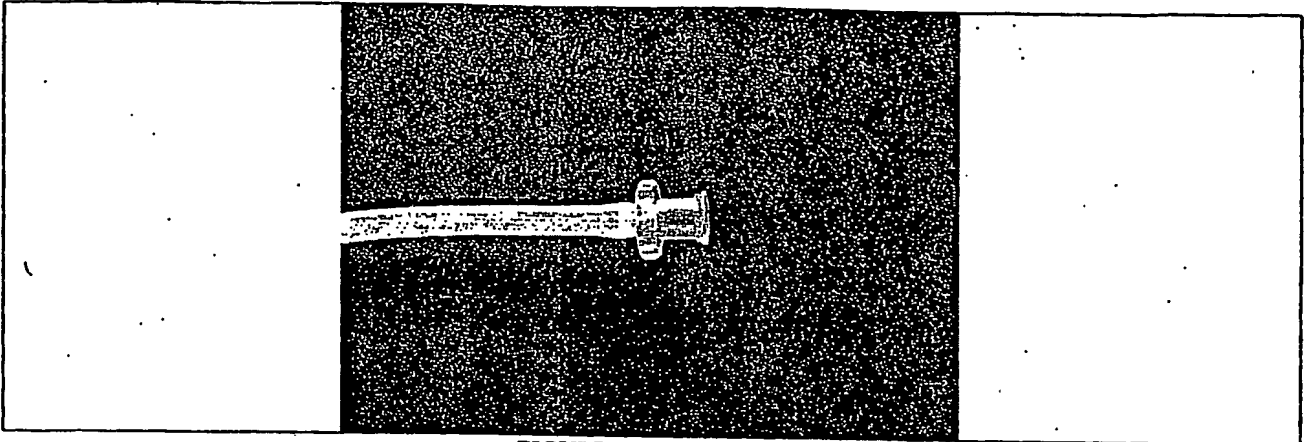


FIGURE 2. Female Luer Fitting Insertion Into Silicone Tubing End

- 4.2.3 Press the smaller barbed end of (Item 8) 3/16" to 1/16" Barb Female Luer Fitting [P/N 200106] fully into the remaining open end of the 6.0" long Silicone Pump Tubing lengths as shown in FIGURE 3.

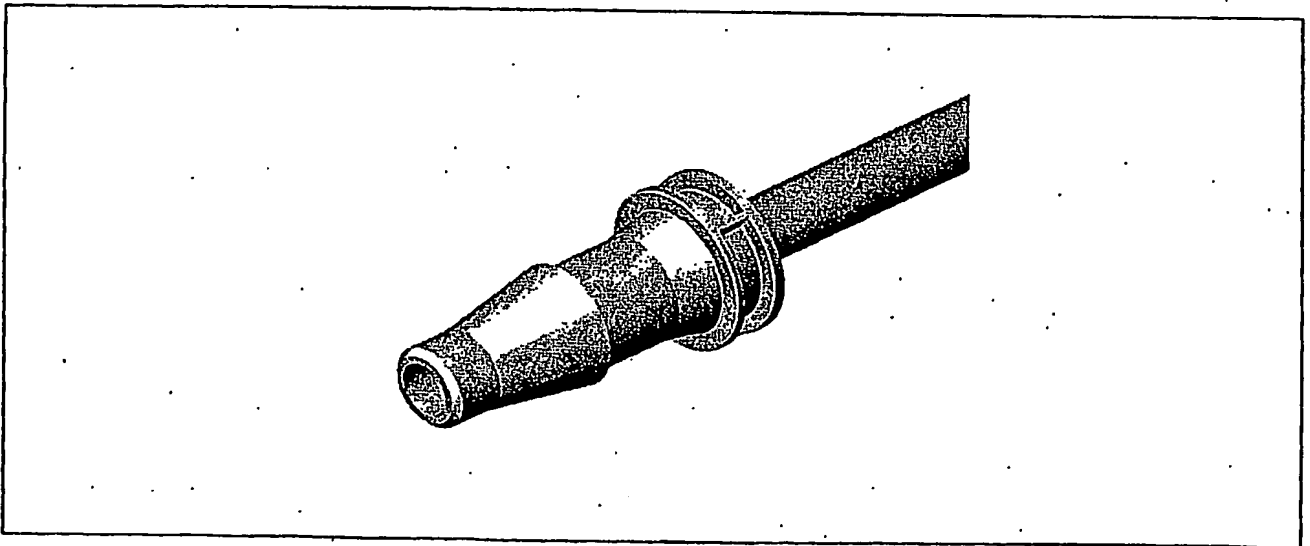


FIGURE 3. Small Barb End Insertion Into Silicone Tubing End

- 4.2.4 Place the tubing assembly with barb fittings into the appropriate bin.

4.3 REMOVING COLLECTION BAG KNOCKOUTS

- 4.3.1 Remove 2 PVC knockouts from the end of the (Item 4) Collection Bag closest to the tubing port with a flat-bladed screwdriver (or equivalent) as shown in FIGURE 4.

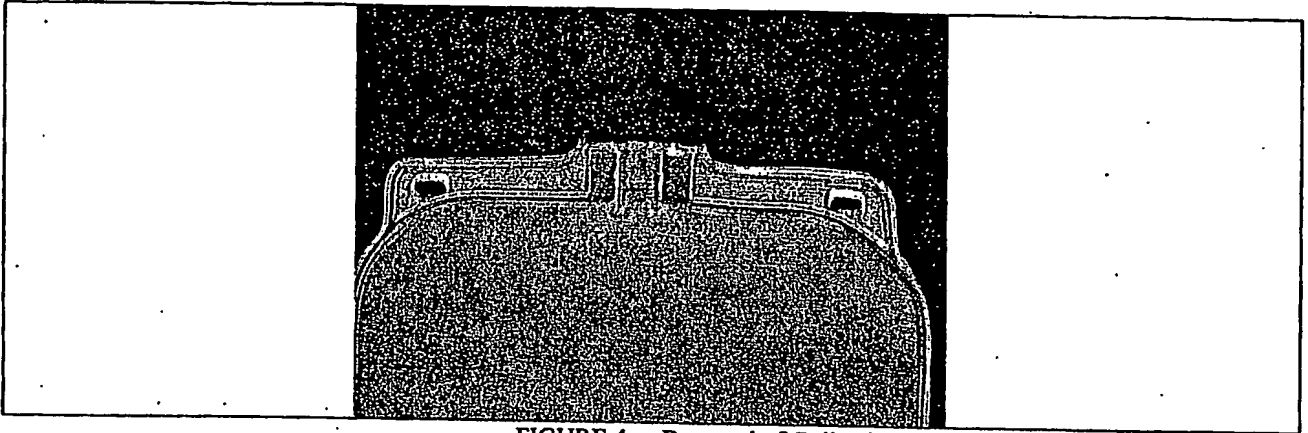


FIGURE 4. Removal of Collection Bag Knockouts

- 4.3.2 Dispose of all knockouts and make sure there are no loose knockouts clinging to the Collection Bag.

4.4 TRIMMING OF COLLECTION BAG TUBING PORT

- 4.4.1 Trim back the 0.24"ID/0.31"OD PVC tubing port of the collection bag so that it is flush with the edge of the RF weld seam edge as shown in FIGURE 5.

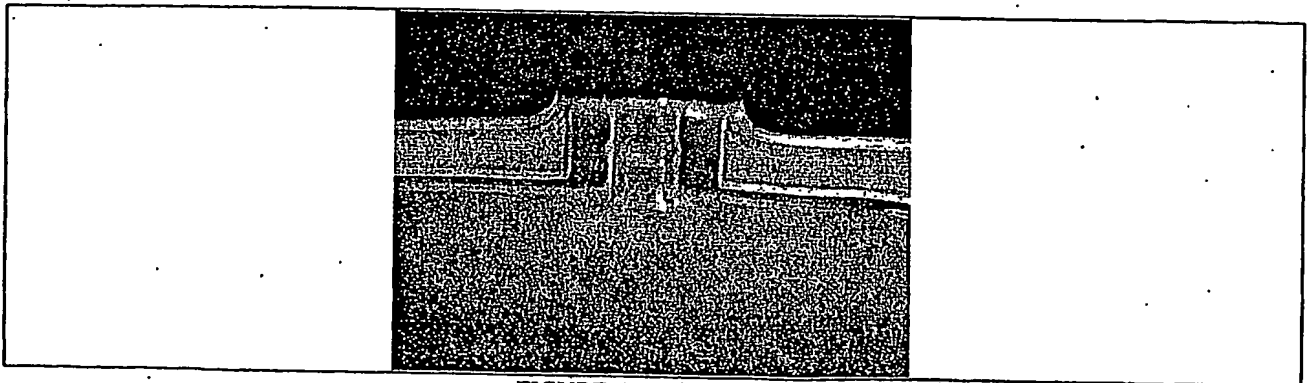


FIGURE 5. Flush Trimming of Collection Bag Tubing Port

4.5 ATTACHING BARBED PUMP TUBING FITTING TO COLLECTION BAG

- 4.5.1 Insert the larger exposed barbed end of (Item 8) 3/16" to 1/16" Barb Female Luer Fitting (previously attached to one end of the 6.0" long Silicone Pump Tubing) fully into the Collection Bag's trimmed tubing port as shown in FIGURE 6.

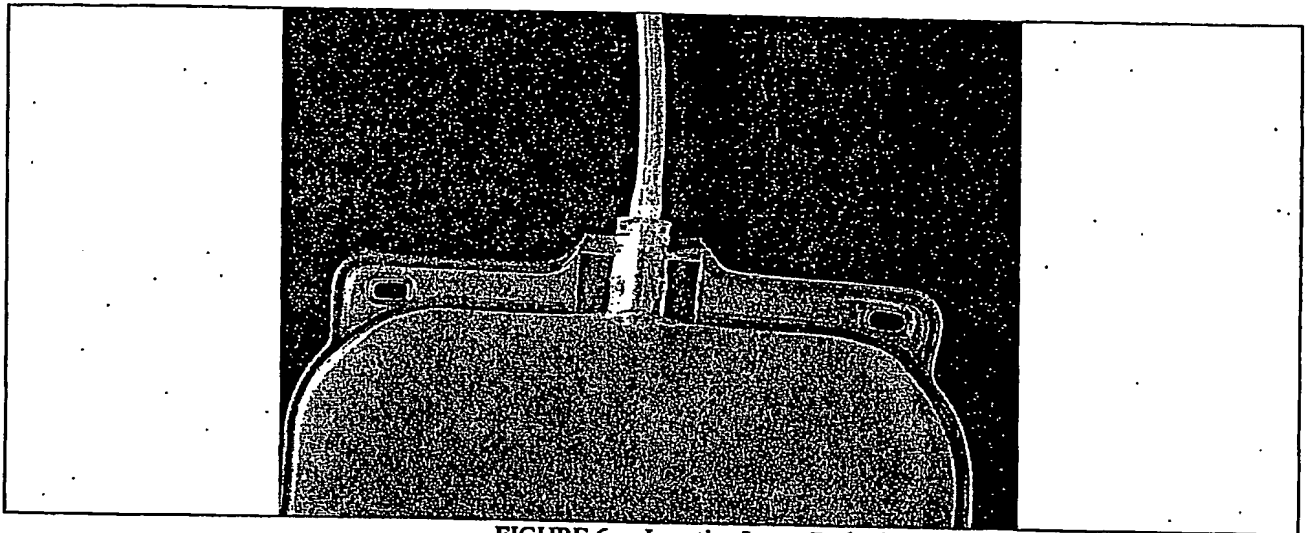


FIGURE 6. Inserting Large Barbed Fitting End into Collection Bag Port

4.6 CONNECTING SYRINGE AND STOPCOCK

- 4.6.1 Remove and discard the pre-attached blue luer cap from the (Item 7) 20mL Polypropylene Syringe [P/N 200100-20].
- 4.6.2 Attach the male luer lock end of the (Item 7) 20mL Polypropylene Syringe [P/N 200100-20] to the central female luer port fitting of the (Item 3) 4-Way Stopcock [P/N 200073] as shown in FIGURE 7.
- 4.6.3 Position the Stopcock's rotating valve handle so that the "OFF" indicator points towards the body of the Syringe. (See FIGURE 7.)
- 4.6.4 Securely connect the only male luer 4-Way Stopcock port to the (Item 5) 1/16" Barbed Female Luer Fitting [P/N 200085] already inserted into one end of the (Item 2) 6.0" long Silicone Pump Tubing length. (See FIGURE 7.)

NEOMEDIX Corporation

Title: MI - Pouched Aspiration Set

MI 450002

Rev. A

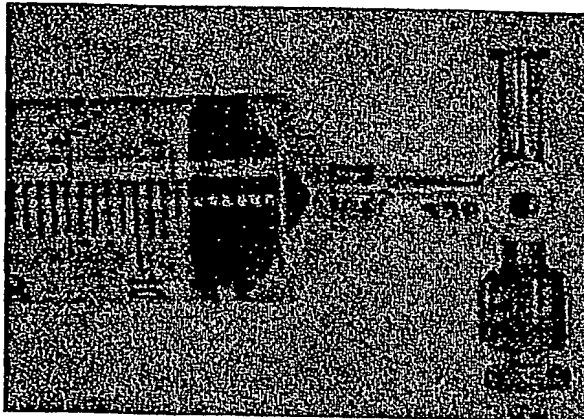


FIGURE 7. Connection of Stopcock and Syringe

4.7 LABELING AND SEALING THE POUCH

- 4.7.1 Apply (Item 7) Aspiration Set Label [P/N 190020] centered on the white Tyvek side of the (Item 1) 10"L x 6"W Tyvek Pouch [P/N 200066] per the orientation indicated on the assembly drawing.
- 4.7.2 Place the assembled items into the 10"L x 6"W Tyvek Pouch as shown in FIGURE 8.

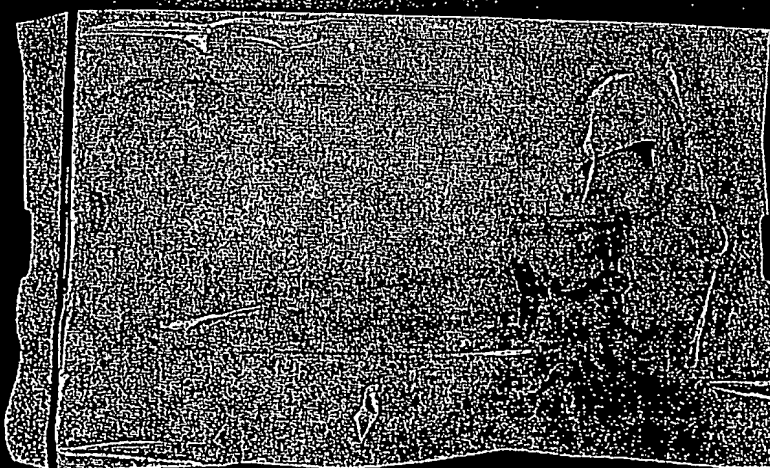


FIGURE 8. Inserting Assembled Items Into Pouch

NEOMEDIX Corporation

Title: MI - Pouched Aspiration Set**MI 450002****Rev. A**

- 4.7.3 Setup and operate the Impulse AutoSealer as described in NeoMedix 850006.
- 4.7.4 Place the finished pouched assemblies into appropriate labeled bins with the Work Order #, Assembly P/N, Lot Number, and Quantity.

NEOMEDIX
Corporation

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60477258 .061003

Manufacturing Instructions

MI 450003

Title: MI - Pouched Handpiece Set

Rev. A

Prepared By: NeoMedix

Release Level: Clinical

ECN No:

Release Approved By:

Date:

421-03

J. Sorenson

04/24/03

1.0 PURPOSE

Details the steps required to assemble the Pouched Handpiece Set [P/N 550003], for personnel experienced in assembling disposable medical devices. The steps include labeling and packaging the pouch, inserting the handpiece into the pouch, sealing the pouches, inserting the sealed pouches with handpieces into a poly-bag, and inserting the poly-bag with pouched handpieces into a container for sterilization.

2.0 TOOLS AND SUPPLIES

- Powder-free exam gloves or equivalent
- Cable Tie or equivalent suitable closure device
- AIE-305A1 Impulse AutoSealer or equivalent
- 200096 Box, Corrugated (17"x13"x13")
- 200091 Bag, Poly (15" x 9" x 32")

3.0 MATERIALS

All materials are listed in the assembly drawing for NeoMedix P/N 550003.

Additional referenced documents:

NMX 850006 Op. Instruction AIE-305A1 Impulse AutoSealer

Confidential

CONTROL DOCUMENT

Page 1 of 4

Title: MI - MI - Pouched Handpiece Set

MI 450003

Rev. A

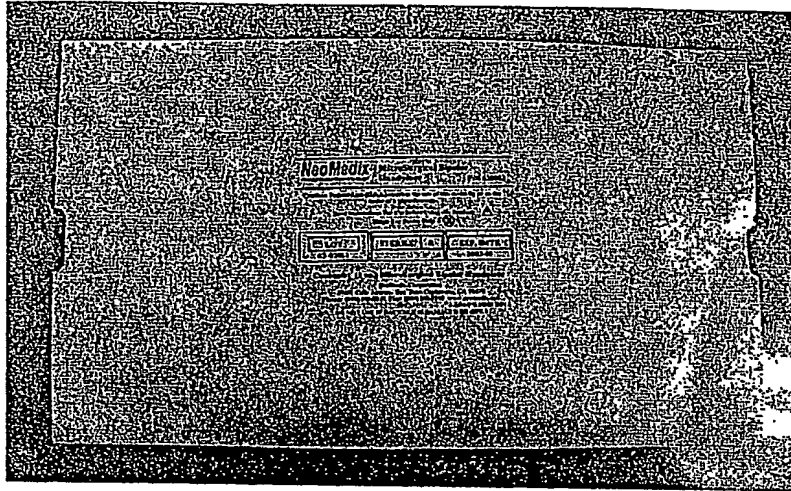


FIGURE 1. Completed 550003 Assembly

4.0 PROCEDURE

4.1 LABELING THE POUCH

- 4.1.1 Apply Microsurgical Bipolar Handpiece Label [P/N 190021] centered on the Tyvek (white) side of the Pouch [P/N 200067] in orientation shown on the assembly drawing.

4.2 HANDPIECE- COILING THE TUBING

- 4.2.1 Connect the male and female luers of the Handpiece Top Assembly [P/N 500021] to the female luer to 1/16" barb and male luer slip to 3/32" barb, respectively, of the I/A Tube Set [P/N 500033] as shown in FIGURE 2.

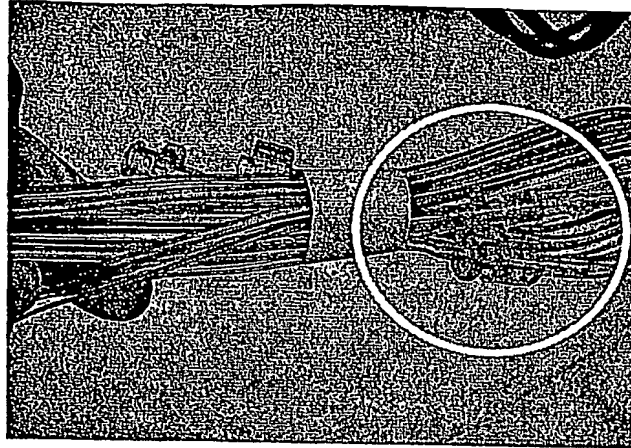


FIGURE 2. Connection of the I/A Tube Set to the Handpiece tubing.

- 4.2.2 Place the handpiece, protective sheath first, into the Tyvek Pouch [P/N 200066] as shown in **FIGURE 3**.

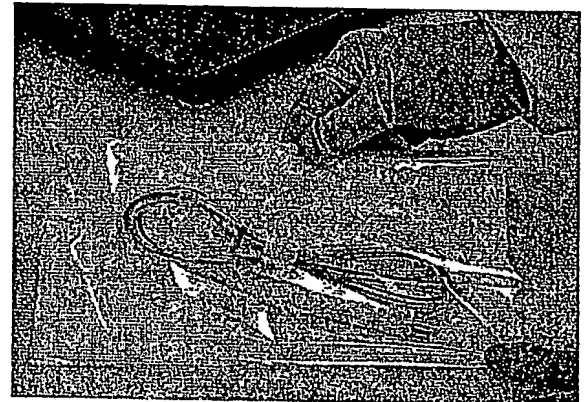
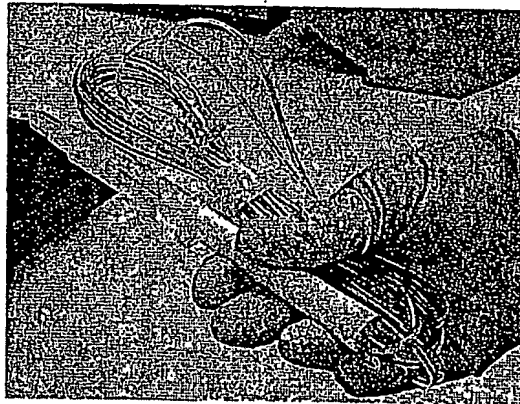


FIGURE 3. Arrangement of the tubing and insertion of the handpiece into the Tyvek pouch.

- 4.2.3 Setup and operate the AutoSealer as described in NMX 850006 to seal the Tyvek Pouch [NMX P/N 200066] with handpiece as shown in **FIGURE 4**.

NEOMEDIX Corporation

Title: MI - MI - Pouched Handpiece Set

MI 450003

Rev. A

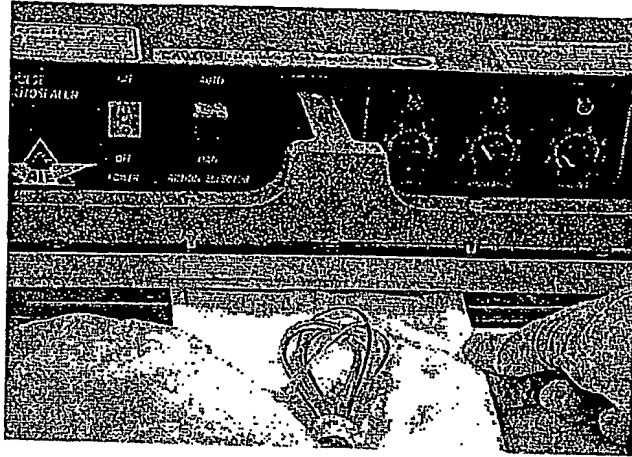


FIGURE 4. Sealing the Tyvek Pouch.

- 4.2.4 Place the sealed Tyvek Pouch with handpiece into Tyvek Pouch [P/N 200067] with attached label [P/N 190021] so that the translucent windows are aligned to allow viewing of the handpiece through the two Pouches.
- 4.2.5 Operate the AutoSealer as described in NMX 850006 to seal the Tyvek Pouch.

4.3 STERILIZATION

- 4.3.1 Place the double-pouched handpieces into a poly-bag [NMX P/N 200091].
- 4.3.2 Ensure closure of the poly-bag by securing the bag with a Cable Tie.
- 4.3.3 Place the closed poly-bag into another poly-bag, thereby double bagging the pouched handpiece, and secure the second bag with a Cable Tie.
- 4.3.4 Package the completed subassemblies into a shipping box for shipping to Gamma Sterilizer for sterilization.
- 4.3.5 Gamma-sterilize units at appropriate dosage. Include sterilization record with units.
- 4.3.6 Return units [NMX P/N 550003] to NeoMedix.

4.4 INVENTORY

- 4.4.1 Place the finished subassembly into appropriate labeled bins with the Work Order #, Assembly P/N, Lot Number, and Quantity.
- 4.4.2 Place sterilization record in document control for filing.

Confidential**CONTROL DOCUMENT**

Page 4 of 4

irrigation
port

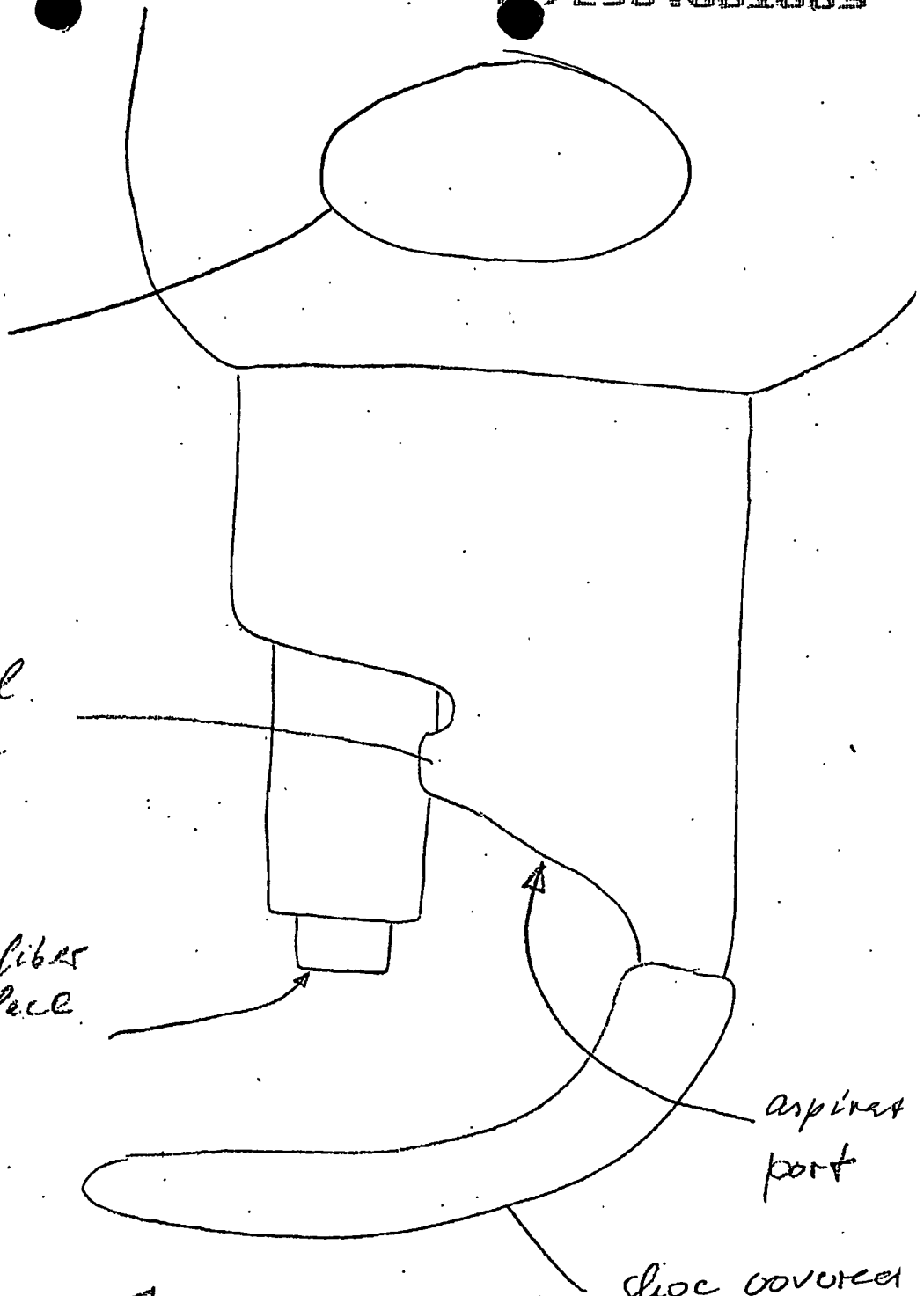
Mechanical
location
of fiber

optical fiber
distal face

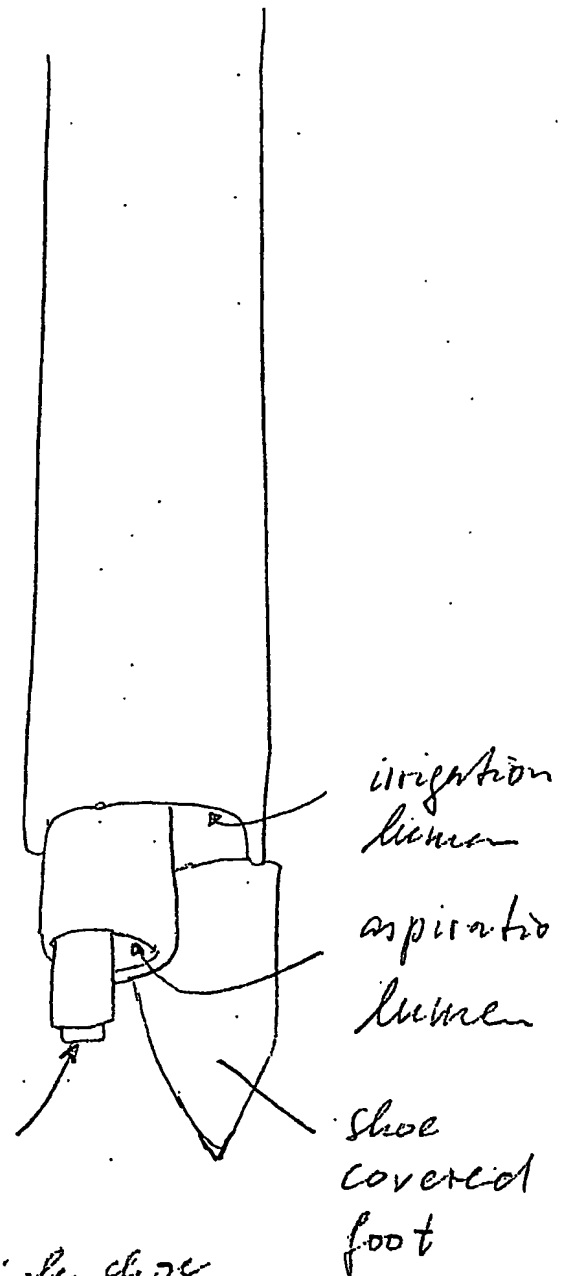
aspirates
port

shoe covered
foot

direction of motion
during surgical
activation

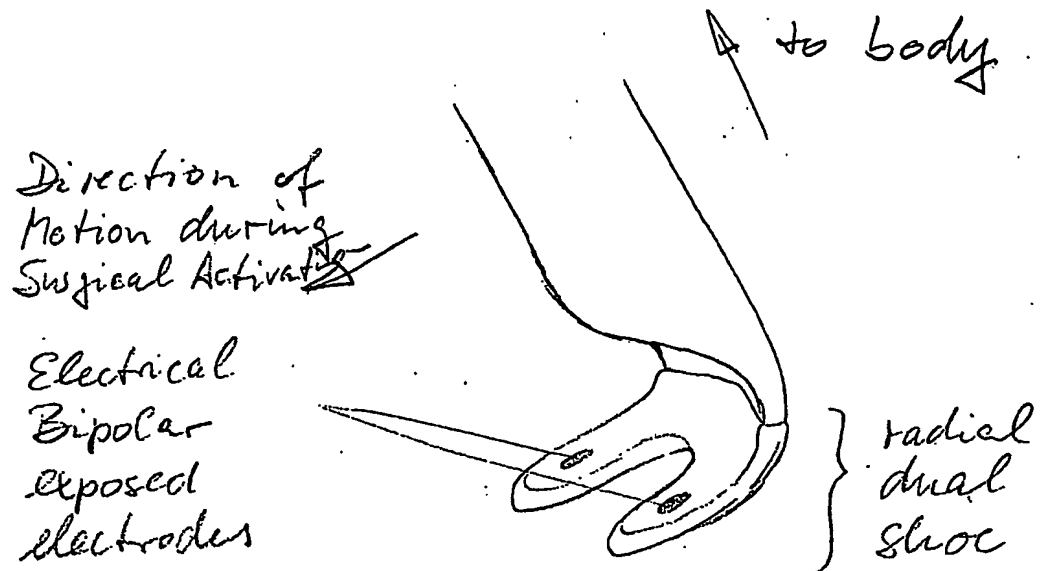


direction of
motion
during
surgical
activation

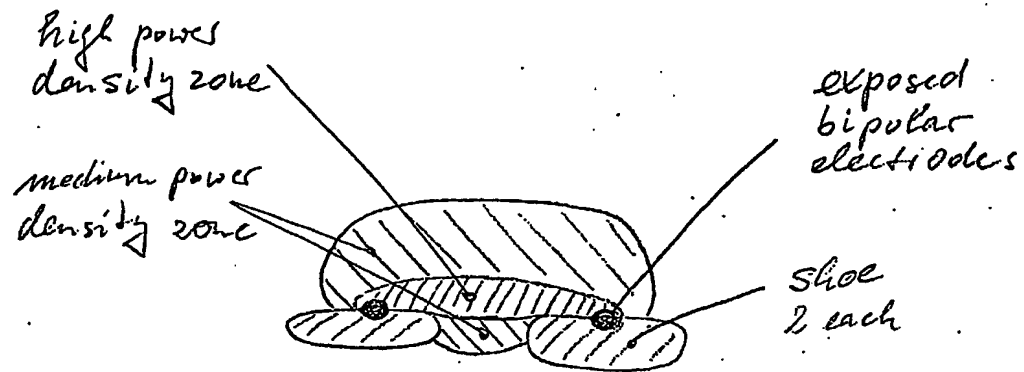


exposed
electrode

Electrical Monopolar, axial single shoe
with pointed forward end



Electrical Bipolar radial dual shoe
blunt forward end



Electrical, Bipolar, radial dual shoe
in cross section

SECTION 4 - DEVICE DESCRIPTION

A. Pictorial Drawings and Photographs of the Device

An overall view of the Handpiece Set is provided in Figure 1. A detail of the Handpiece alone is shown in Figure 2. A detail of the Handpiece probe is shown in Figure 3. A detail of the probe distal portion is shown in Figure 4. A close-up detail of the electrode probe is shown in Figure 5. Photographs of the three components of the set are shown in Figures 6 – 9.

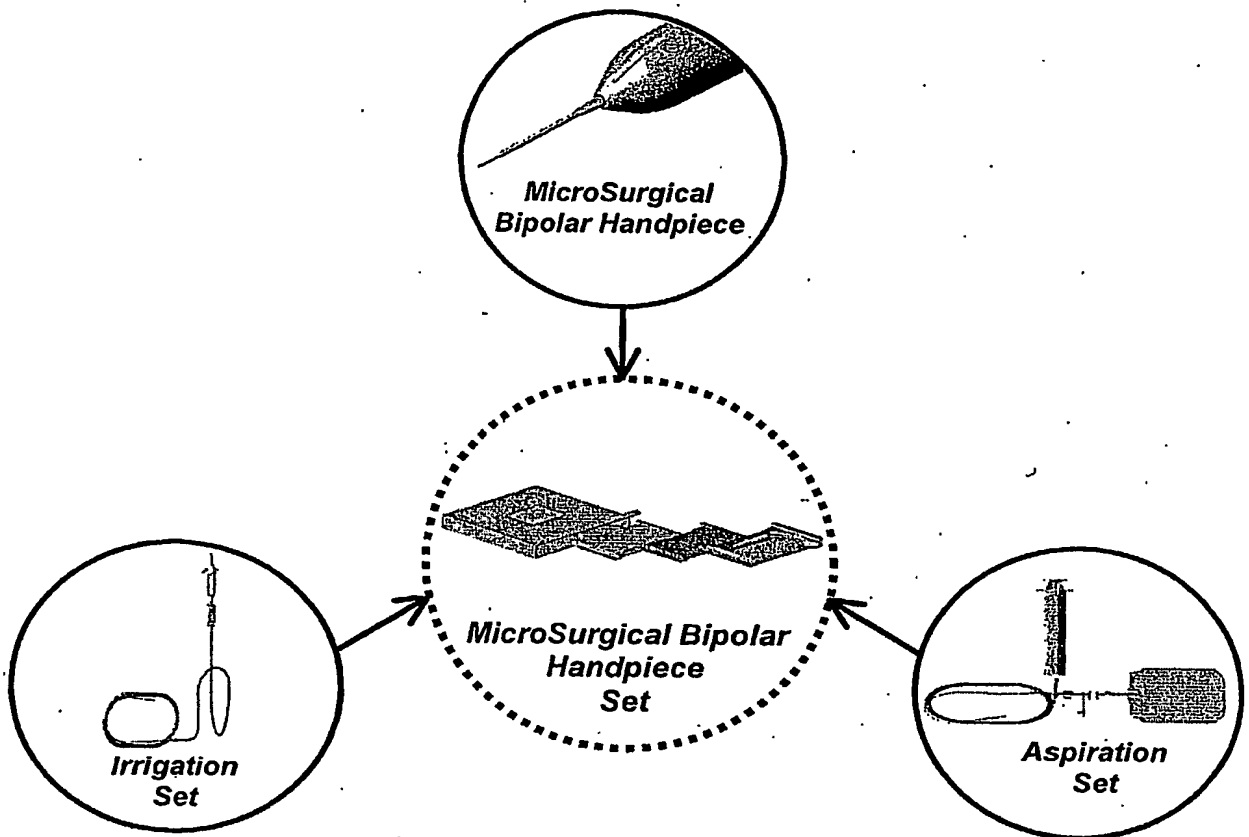


Figure 1 – Handpiece Set

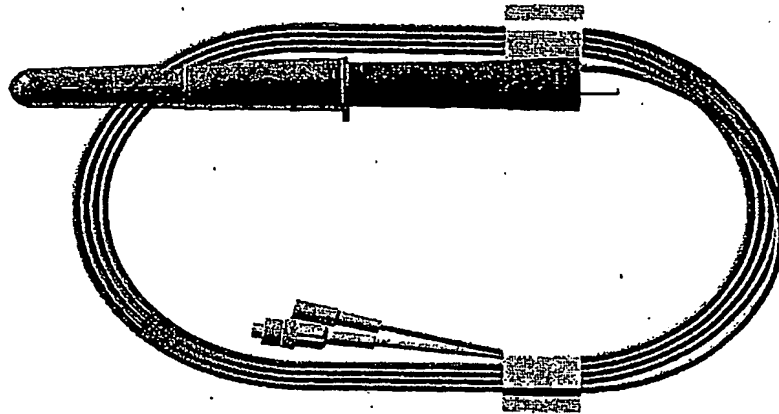


Figure 2 – Handpiece

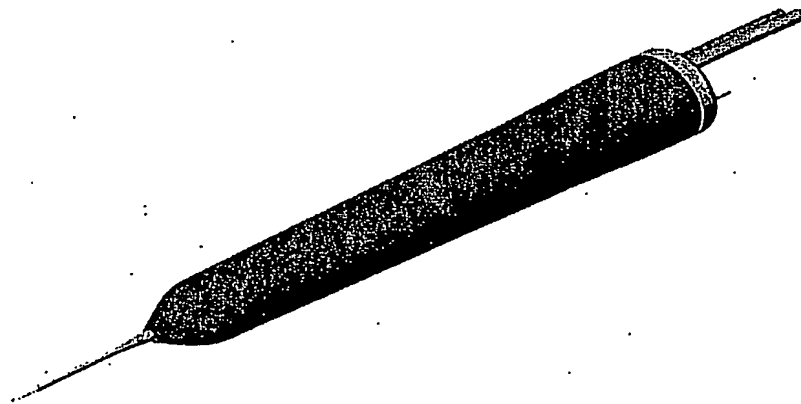


Figure 3 – Handpiece Probe

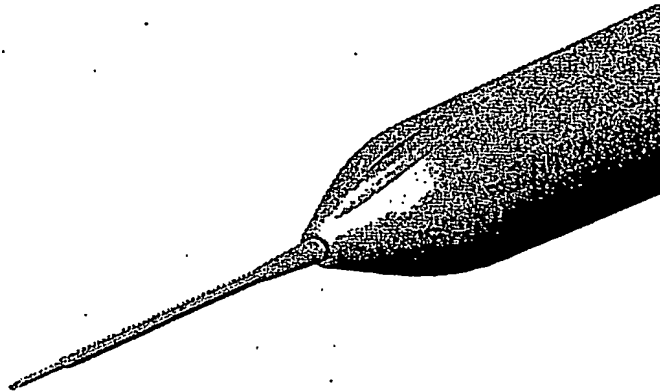


Figure 4 – Probe Distal Portion

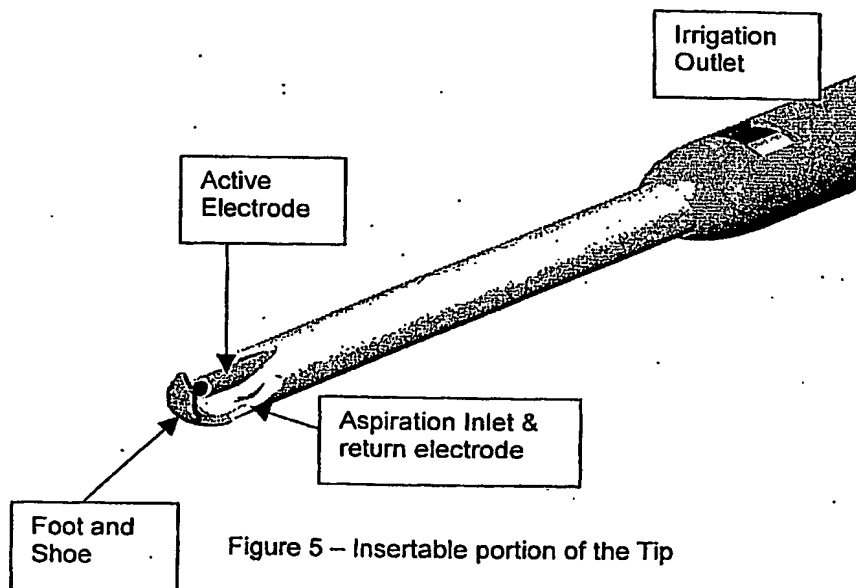


Figure 5 – Insertable portion of the Tip

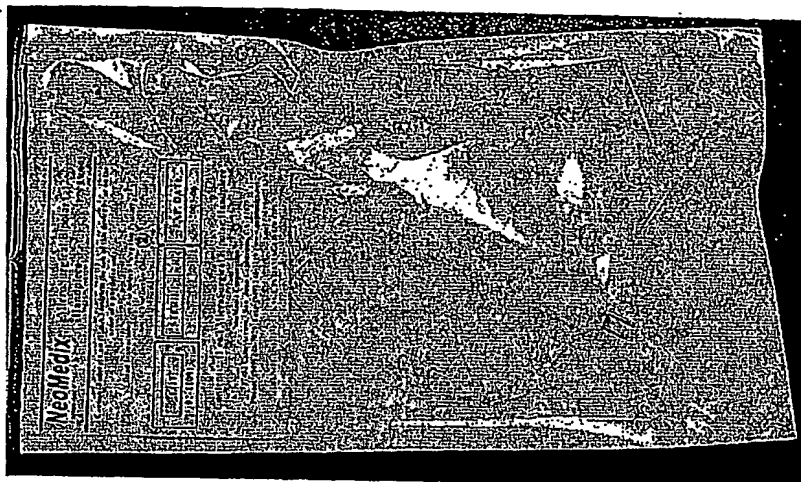


Figure 6 -Packaged Handpiece

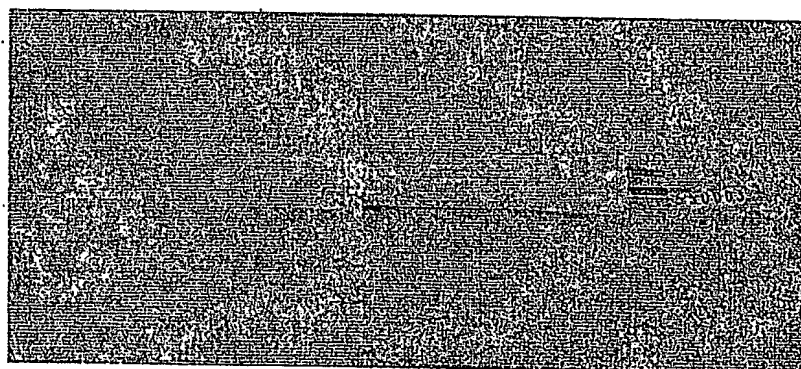


Figure 7 – Handpiece with P/N ID

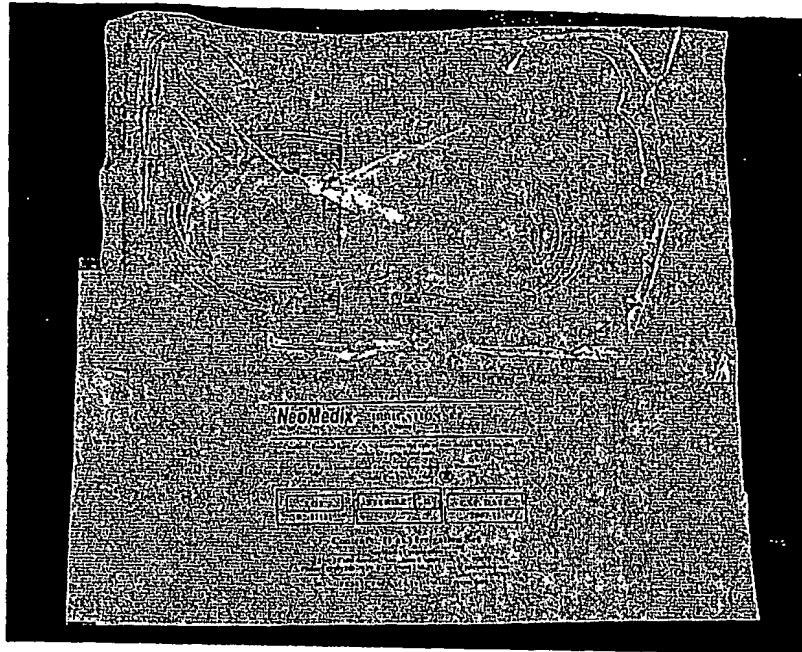


Figure 8 – Packaged Irrigation Set

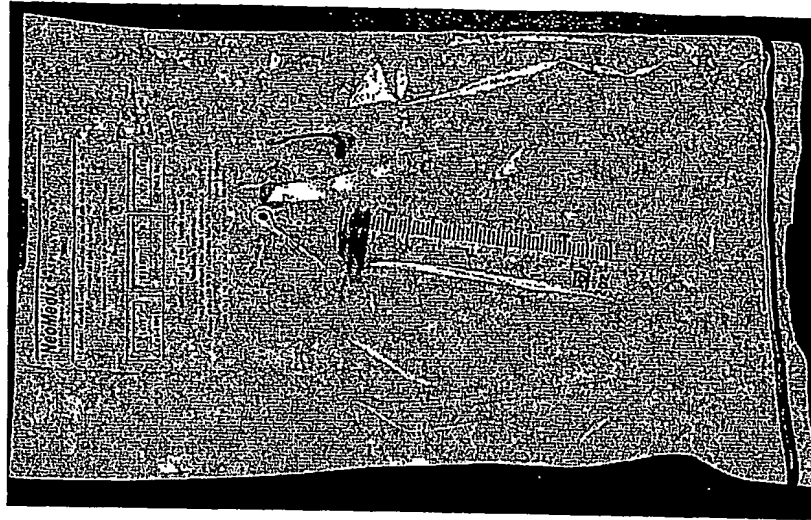


Figure 9 – Packaged Aspiration Set

B. Principles of Operation

The Handpiece is designed to operate in the bipolar mode when connected to any compatible electrosurgical generator capable of low energy output control.

The Handpiece contains irrigation and aspiration channels that are connected to medical grade tubing. The irrigation line is connected to a bag or bottle, which is hung from an I.V. pole, providing gravity induced fluid flow, which is controlled with a roller clamp or pinch valve. The aspiration line is designed to be connected to a syringe or peristaltic pump for collecting aspirant.

C. Design Features

The Handpiece is a single-use disposable, handheld instrument. The Handpiece is connected to a fluidic system providing for both irrigation and aspiration and to any radio frequency electrosurgical unit that has low power output control. The Handpiece is designed to be grasped like a fountain pen.

Foot: The radially positioned feature at the distal end of the probe that is designed to aid in entering the targeted tissue. The "foot", aspiration tube and return electrode are common (the same stainless steel member).

Shoe: A conforming insulating polymer coating (polyimide) which facilitates guiding the foot and electrically isolates the foot from the underlying tissue. The coating helps assure that the radio frequency current path is limited to the gap between the bipolar electrodes within the tip.

Working End: The distal portion of the Handpiece tip comprising the foot with the shoe, the distal end of the active electrode, the return electrode, the aspiration port and the mechanical portions that hold these components in relative position. The foot and shoe facilitate insertion and positioning into the targeted tissue while the electrode facilitates cutting or coagulation by radio frequency current.

Insertable Portion of the Tip: The distal portion of the Handpiece tip comprising the working end and the distal portion of the irrigation and aspiration channels. The irrigation channel provides a rinsing action and enhances the "wet field" for a constant bipolar conduction path. The aspiration channel provides a means of removing unwanted debris in the surgical field.

D. Device Specifications

The device specifications are summarized in Table I; the NeoMedix product drawings are provided in Section 12, Attachment III.

NeoMedix Microsurgical Handpiece

Feature	Function/Requirement	Dimensions/Description	Material
Handpiece body	Encapsulate electrical and fluidic members	0.45" to 0.68" diameter by 4.5" long	ABS plastic
	Electrical protection; 3000V _{RMS}	Conforms to ANSI/AAMI HF-18	
	Leakage current 817V _{RMS}	Conforms to IEC 60601-1 Sub-clause 19.3	
Handpiece probe	Coaxial tapered bipolar electrode with insulated foot	18 – 25 gauge, approximately 1" long;	Stainless steel with polymer insulation
	Dielectric must withstand 300V _{RMS}	Dielectric test to verify coating integrity	-
	Active electrode	Approximately 0.005" diameter	Stainless steel with polymer insulation
	Return electrode	Common to aspiration tube and adjacent to the active electrode	Stainless steel
	Power capability	1.5 watts maximum	-
	Irrigation/aspiration	Integral to probe	Stainless steel
Electrosurgical Unit (ESU) connector	Compatible electrical connection to bipolar probe	Standard two pin plug; pins 0.078" diameter	Nickel silver
ESU Compatibility	RF generator or coagulator with low power output/control	Hospital supplied	-
Irrigation/Aspiration tubing	Connection to fluidic accessories	Approximately two meters long with luer connections	Tygon
Sterile package	Handpiece, Irrigation and Aspiration sets	6" X 9" Pouch (3) packaged as a set	Tyvek®/Poly
Sterility	SAL of 10 ⁻⁶	Gamma radiation	-
Risk analysis	EN 1441	Risks identified and acceptable countermeasures incorporated	-

Table I
Product Specifications Summary Table

E. Physical Characteristics

Dimensions and Tolerances

All specified dimensions are considered nominal unless otherwise indicated. Appropriate tolerances are specified on component and assembly drawings.

Overall

1. The body of the Handpiece is ergonomically contoured having circular cross sections to fit in the hand like a fountain pen.
2. The body diameter in the gripping region is 0.450" diameter, while the rear of body is 0.680" diameter. The body of the Handpiece is made of white ABS plastic.
3. The stainless steel probe tip is approximately 1 mm in diameter and protrudes from the body approximately 2.5 cm.
4. Two flexible transparent tubing lines emerge from the proximal end of Handpiece to provide for irrigation and aspiration capability.

Irrigation Tube

1. The tube is fabricated from electro-polished 305 stainless steel and contains two (2) side outlet ports across from and positioned parallel to the integral foot.
2. The irrigation channel supports a flow rate of at 3.0 ml/min.

Aspiration Tube/Return Electrode

1. The tube is fabricated from 304 or 316L stainless steel tube stock and supports a flow rate of 4.0 ml/min.
2. The aspiration tube is also the "return" electrode for the bipolar electrical connection to the radio frequency generator.

Active Electrode

1. The active electrode is fabricated from 304V stainless steel.
2. The electrode is insulated with polyimide tubing surrounding the electrode.

Insulating Shoe

1. The insulating shoe on the probe foot consists of a polyimide conformal coating (essentially equivalent to the active electrode insulation).
2. The polyimide coating can withstand 300V_{RMS} continuously applied without breaking down.

Irrigation/Aspiration Tubing

1. The tubing attached to the Handpiece is Tygon S-54HL medical grade material approximately two (2) meters in length
2. The irrigation tubing is terminated proximally with a female luer lock connector; the aspiration tubing is terminated proximally with a male luer lock connector.

F. Accessories

The irrigation/aspiration sets are provided for convenience purposes. These accessories are Class I devices and are subject to General Controls but not to a 510(k) notification. The standard Accessories include:

Irrigation Set

1. The irrigation set consists of a medical grade single port I.V. line provided sterile to NeoMedix.
2. The irrigation set is comprised of PVC tubing terminated on one end with a standard I.V. spike with drip chamber and on the opposite end with a male luer slip fitting. A roller clamp is included to permit fluid control.

Aspiration Set

1. The aspiration set is fabricated by NeoMedix and sterilized by gamma radiation. All components are medical grade materials that are widely used in the medical industry and do not pose any new safety issues. All materials are "gamma friendly".
2. The aspiration set consists of the following components:
 - a. PVC collection bag
 - b. Gamma grade polycarbonate male luer fitting
 - c. Gamma grade polycarbonate stop cock
 - d. 60ml polypropylene syringe
 - e. Tygon S50-HL medical grade tubing
 - f. Polyethylene luer cap & lanyard
3. The aspiration set is sterilized by gamma radiation.

G. Packaging

The Handpiece, Irrigation Set and Aspiration Set are packaged as a set. Each device is packaged in a Tyvek® pouch with the appropriate label and inserted into a single carton. All materials are known to have at least a three-year shelf life. See Figure 10 below.

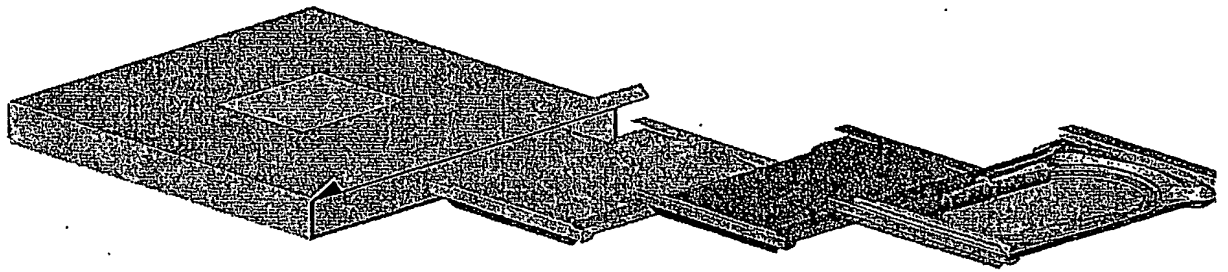


Figure 10 – Packaged Set

Strip of meshwork is removed to prevent it from collapsing into the canal.

Sources: HealthCorp., San Juan Capistrano; Dr. George Baerveldt, UCI National Eye Institute/Glaucoma Research Foundation; "Text Book of Glaucoma," by Dr. M. Bruce Shields "Understanding and Treating Glaucoma," by J. H. Peters and Co. Inc.

NeoMedix Confidential
April 4, 2003

Disclosure: Features for NeoMedix's Selective Tissue Cutting and Coagulation Technology

The instrument having and method utilizing 1) a general proximal end for holding, attaching, inclosing or affecting a power-source, attaching irrigation supply and aspiration disposable collection, being outside the patient, 2) an elongated body, 3) a general distal end for the working end of the instrument. The elongated body (2) may mainly be a handpiece, a catheter, or an autonomous body.

The instrument and method to utilize a foot and shoe instead of a foot plate specifically expressing the **non-homogeneous properties of this member of the device**; whereby the differentiation is based on application specific properties like a stiff foot member which is electrically and thermally conducting with a shoe member which is electrically and thermally insulating and structurally less stiff. The shoe member is covering conformal at least on one side of the foot member.

The instrument and method to utilize a power delivery system which provides a high power density zone at its working end. This high power density zone is considered to be surrounded by a medium power density zone still fully capable of tissue disintegration under suitable operation. The outer bound of this zone is hereby termed the **Reach** of the power delivery system. Limiting and controlling the Reach of the power delivery system is of prime interest due to its limit and control of effecting tissue not only regarding which part of the tissue is going to be disintegrated but also regarding which part of the tissue is going to be kept unaffected in particular with respect to heat damage etc.

Since the instrument is not only used to dissect tissue but also to remove a portion of the tissue the Reach is also significant in a lateral direction: Defining the lateral direction as perpendicular to the direction of motion of the instrument in the active state the **lateral Reach** will define the stripe width of tissue removed which is significant for the size of opening created by the application of the instrument.

Options for the tissue disintegrating power system of the instrument and method include

- ❖ **Mechanical, manually or motor operated**
 - **Knife Cutting:** an implementation could be based on a plurality of knife edges so that a stripe of tissue could be dissected and made available for removal.
 - **Scissor Cutting:** an implementation could be based on a plurality of straight scissor edges or a curved scissor edge so that tissue could be dissected in a stripe pattern by multiply applying scissor action and made available for removal. In this case the high and medium power density regions are considered identical and the reach is defined by the material dissecting effect of the cutting edges.
- ❖ **Optical, incoherent high intensity light or laser light**
 - **Thermal:** an implementation could be based on a fiber or other kind of light guiding delivery system which on its working end exposes the tissue to high

intensity radiation that through absorption in the tissue creates localized heat disintegrating the tissue. In this case the high power density region is defined by the region of majority of the absorption of the light and the medium power density regions is defined by the heat effected zone in which tissue disintegration happens.

- Appellation: an implementation could be based on a fiber or other kind of light guiding delivery system which on its working end exposes the tissue to high intensity radiation (for instance UV light) that appellate tissue. In this case the high power density region is defined by the region of tissue evaporation by the impact of the light and the medium power density regions is defined by the effected zone in which tissue disintegration happens.
- ❖ Electrical, dominantly voltage, dominantly current or voltage and current combination driven
 - Monopolar: an implementation could be based on an insulated electrical conductor connected to an exposed electrode at the working end and an exposed or capacitatively coupled grounding electrode of much larger area place adjacent to the working end or elsewhere in contact with the patient.
 - Bipolar: an implementation could be based on electrical conductors insulated at least from each other connected to exposed electrodes all placed at the working end.

In this case the high power density regions are considered the region in which the majority of the electrical power is disposed with high density, while the medium power density zone is defined by the thermal effect coursing material disintegration.

- ❖ Ultrasound, high acceleration oscillatory movement of an exposed surface
 - Axial through end of a rode or tube: Initial power delivery is distally
 - Radial through exposed side of distal end of a transversely excited rode or tube: Initial power delivery is radial

In this case the high power density regions are considered the region in which the ultrasound power courses cavitation; while the medium power density zone is defined by the chock-wave effect that coursing material disintegration

The instrument and method to utilize a foot and shoe with the function to localize the power delivery for tissue disintegration such that

- ❖ in the case of a homogenize tissue the zone of tissue disintegration is limited by
 - physically limiting and controlling the Reach of the power delivery system and the placement of tissue therein at least on one side
 - thermally insulating tissue at least on one side of the power delivery system's working end
 - optically limiting and controlling the Reach of a radiating power delivery system at least on one side
- ❖ in the case of a heterogenic dual material tissue (for example a soft tissue mass surrounded by a thin tuff membrane like layer) the zone of tissue disintegration is limited by
 - physically wedging the foot and shoe into the interface such that only one of the two kinds of tissue is placed in Reach of the power delivery system such that the first case applies

- physically placing the foot and shoe onto the thin tuff membrane like layer such that it and only a surface layer of the second kind of tissue is placed in Reach of the power delivery system such that the first case applies.
- ❖ in the case of a thin tissue layer the zone of tissue disintegration is limited by
 - physically limiting and controlling the Reach of the power delivery system at least on the fare side of the thin tissue layer
 - lifting the thin tissue layer and thereby physically removing it distanced even further from the underlying tissue as well as stretching and possibly thinning the layer of tissue to be removed and thereby possibly altering the effective lateral reach with respect to the width of the stripe of tissue removed as measured in the un-stretched state.

The instrument and method to utilize a foot and shoe in a particular placement with respect to the power delivery system

- ❖ axial, that is in general parallel to the direction the working end is disposed with respect to the elongated body of the instrument
 - a single member having a foot and a shoe component to it effecting a radial shielding towards at leased one side
 - a plurality of members each having a foot or a shoe component or both effecting a radial shielding towards at leased one side, however, with interruptions such that localized an at leased limited exposure of tissue at said side is provided for a preferred motion along the length of the foot and shoe this configuration is more suitable to cut and remove an axial positioned stripe of material
- ❖ radial, that is in general perpendicular to the direction the working end is disposed with respect to the elongated body of the instrument
 - a single member having a foot and a shoe component to it effecting a distal shielding
 - a plurality of members each having a foot or a shoe component or both effecting a distal shielding, however, with interruptions such that localized an at leased limited exposure of tissue at said side is provided for a preferred motion along the length of the foot and shoe this configuration is more suitable to cut and remove a radial positioned stripe of material
- ❖ tangential, that is in general perpendicular to the direction the working end is disposed with respect to the elongated body of the instrument and offset sideways
 - a single member having a foot and a shoe component to it effecting a sideways shielding
 - a plurality of members each having a foot or a shoe component or both effecting a sideways shielding, however, with interruptions such that localized an at leased limited exposure of tissue at said side is provided for a preferred motion along the length of the foot and shoe this configuration is more suitable to cut and remove a tangential positioned stripe of material

The instrument and method to utilize directionality of the power delivery systems to further define the location of the high power density zone and the medium power density zone with respect to the foot and shoe. Some of the power delivery options allow for at

least initial directional power delivery for example optical by setting the direction of the emerging light by corner mirrors.

The instrument and method to utilize a foot and shoe with a particular shape on its forward (in the direction of advancement when moved in the surgical application) portion to effect

- ❖ a sharp point for penetration into tissue
- ❖ a sharp edge a cut into tissue
- ❖ a blunt (bullet nose) point to gently non-forcing separate particular soft tissue
- ❖ a blunt wedge to gently separate layers in particular layers of dissimilar tissue

Particular configurations of interest include a radial dual member foot and shoe which can be used to dissect free a membrane that is in small locations attached to a delicate underlying tissue. The two shoes provide the protection and spacing of the Reach above the delicate tissue. The two feet hold the members for the power delivery system for instance bipolar electrosurgical electrodes. The dual feet and shoe configuration allows the device to be placed around the attachment points in a upside down horse shoe shape and the electrosurgical power application effects the decisive disruption of the small locations of attachment. The placement of the device helps to also lift said membrane of said delicate underlying tissue to dissect said two tissues.

The instrument and method to utilize fabrication approach and method for a foot and shoe joining

- ❖ assemble individual prefabricated parts
 - adhesive
 - welding
 - crimping
 - friction fit
 - snap in utilizing flexing of members temporarily during the process of joining
 - reshaping material into more locked configuration by
 - mechanical deformation
 - thermal re-flow
- ❖ co-fabrication of at least one of the members
 - over-molding
 - insert casting
 - coating
 - single layer dip coating
 - multi layer dip coating
 - painting
 - powder (electro statically)
 - vapor deposition

The instrument and method to utilize fabrication approach and method for a foot of feet

- ❖ molding

- ❖ casting
- ❖ billet carving
- ❖ fabrication from a flat, tubular or drawn pre-form with or without sub-sequential shaping like bending
 - stamping
 - laser cutting
 - water-jet cutting

The fabrication approach and method for a foot may in particular be an integrated approach providing for multiple functions for the instrument in the part produced

- ❖ locating the distal end of the power delivery system with respect to the foot
- ❖ providing the structural member to the body of the instrument
- ❖ providing irrigation function to the working end
- ❖ providing aspiration function to the working end
- ❖ providing protection of the power delivery channel to the working end

The instrument and method to utilize fabrication approach and method for an irrigation channel

- ❖ fabrication from a tubular or drawn pre-form with or without sub-sequential shaping like bending
 - stamping
 - laser cutting
 - water-jet cutting
 - drilling
 - pricing

The fabrication approach and method for irrigation channel may in particular be an integrated approach providing for multiple functions for the instrument in the part produced

- ❖ locating the distal working end with respect to the body
- ❖ providing part of the body itself
- ❖ locating the aspiration channel at and towards the working end

The instrument and method to utilize power application during activation with timing profile of

- ❖ continuous
- ❖ pulsed, with a fixed pulse shape that is continuously reproduced
- ❖ super pulsed, where the pulse shape itself is composed of a sequence of pulses

NeoMedix Confidential
April 3, 2003

**Disclosure: Medical Uses for NeoMedix's
Selective Tissue Cutting/Coagulation Technology**

NeoMedix is developing a technology that allows for *selective* tissue cutting/coagulation, meaning that elements of the device are designed such that closely adjacent tissues are simultaneously and selectively shielded from said cutting/coagulation effects.

Although device means for such selective tissue cutting/coagulation are described in accompanying disclosure(s), the purpose of this disclosure is to identify certain medical applications for which said selective tissue cutting/coagulation would be particularly advantageous compared to conventional tissue cutting/coagulation approaches.

For ophthalmology, the particular medical use for removal of trabecular meshwork while protecting the underlying tissues of Schlemm's canal has been previously described. The following are believed to be potentially novel medical uses for NeoMedix's technology:

1) Detachment of Retinal Membrane Overgrowths in the Posterior Segment of the Eye

As a result of certain diseased states, primarily related to diabetes, membranous overgrowths can develop in the vitreous chamber of the eye covering regions of the retina. Because vision is obscured as a result of such membranous overgrowths, posterior segment surgery is performed to carefully detach and remove these membranous overgrowths. Care must be taken to minimize trauma to the underlying retina and to avoid bleeding as the mechanical and sometimes vascularized attachments of the membranous overgrowths are detached. Current means include use of small mechanical cutters which often lead to bleeding that may require cauterization. NeoMedix's selective tissue cutting/coagulation technology would provide a potentially superior means of being able to cut the attachments to the retina while minimizing bleeding and shielding/protecting the underlying retina from thermal or other trauma.

2) Selective Cauterization of Retinal Vessels in the Posterior Segment of the Eye

As a result of certain diseased states, often related to diabetes, retinal vascular abnormalities can occur. Initially, diabetic retinopathy often involves weakening and bleeding from retinal vessels. In later stages, new vessels often begin to proliferate and even grow into the vitreous, obscuring vision. Treatment often involves focal laser photocoagulation, where a laser is used to create tiny spots of photocoagulation, either directed or scattered across the retina. NeoMedix's selective tissue cutting/coagulation technology could provide an effective means of selectively coagulating vessels of the

retina or extending from the retina while limiting the thermal trauma to adjacent retinal tissue.

3) Gum Dissection

Often dental procedures and oral surgical procedures involve gum dissection. These dissections are often performed near teeth, roots, nerves, or other sensitive structures. In addition, gum tissue is highly vascularized and cutting leads to significant bleeding. NeoMedix's selective tissue cutting/coagulation technology could provide a superior means for cutting of gum tissue while protecting adjacent sensitive tissues and structures and reducing bleeding.

4) Dermatology Procedures

Dermatology procedures involve selective ablation of particular growths, cutting of skin where depth of trauma needs to be controlled to protect underlying tissues, and requires control of bleeding. NeoMedix's selective tissue cutting/coagulation technology would provide a means for performing such procedures wherein the energy could be applied in such a manner as to provide distinct advantages for said procedures.

5) Selective Ablation/Removal of Tumors or Other Tissue Growths

Cancerous tumors and other abnormal tissue growths often challenging or deemed "inoperable" because of being located adjacent to or too intimately with vital organs or sensitive tissues. NeoMedix's selective tissue cutting/coagulation technology would provide surgeons with a means for better directing the energy used for tumor ablation and removal allowing for such procedures to be better performed in the vicinity of vital organs or sensitive tissues. In addition, such procedures could also be performed with less trauma to adjacent normal tissues, even if they are not particularly vital or sensitive, reducing healing time and limiting the local trauma.

6) Brain and Neurological Surgical Procedures

Neurological procedures and brain surgery often involve delicate tissue cutting and/or removal or treatment of hemorrhagic sites in close proximity to nerves and/or sensitive tissues such as brain tissue. In these cases, NeoMedix's selective tissue cutting/coagulation technology could offer the advantage of facilitating such tissue cutting and/or removal or treatment of hemorrhagic sites while minimizing trauma to such adjacent nerve or brain tissues.

7) Vocal Cord Surgery

The vocal cords are often effected by abnormal growths that must be carefully removed while minimizing damage to the delicate vocal cords. NeoMedix's selective tissue cutting/coagulation technology would offer the surgeon a superior means of removing

these abnormal growths while minimizing exposure of the adjacent vocal cord tissues to trauma.

8) Heart Surgery

NeoMedix's selective tissue cutting/coagulation technology may offer an effective means of cutting the membranous tissue structures of the heart, including the pericardium and endocardium while protecting the underlying myocardium and/or the critical vascular structures that perfuse the heart. Catheter-based or minimally-invasive implementations NeoMedix's selective tissue cutting/coagulation technology could also be advantageous for selective ablations and tissue valve procedures.

8) Liver Dissection

Surgical procedures on the liver often require cutting of liver tissue while controlling bleeding and minimizing trauma to the larger vascular structures that crisscross the hepatic tissues in a complex array. NeoMedix's selective tissue cutting/coagulation technology would offer the surgeon a superior manner of controlling bleeding while cutting through liver tissue and minimizing damage to adjacent vasculature and tissue.

9) ENT Surgical Procedures

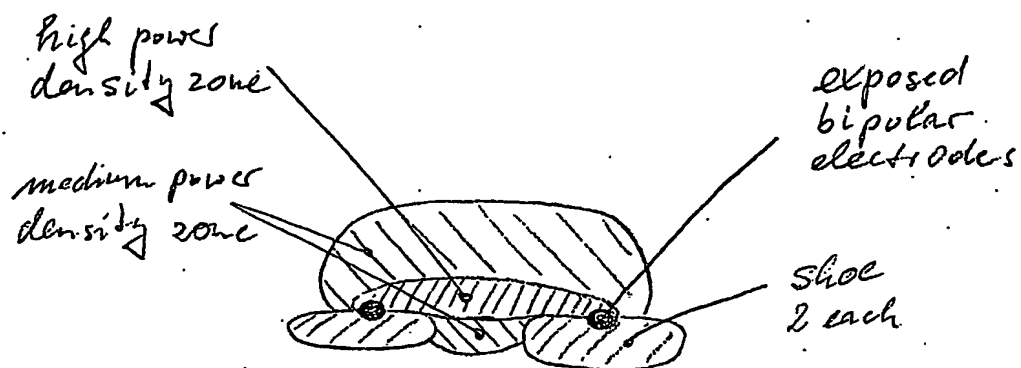
ENT surgical procedures often involve working in small confined passageways (for example the sinuses) to cut/coagulate tissue near sensitive adjacent structures and tissues. NeoMedix's selective tissue cutting/coagulation technology would offer the ENT surgeon a means for operating in very confined spaces while selectively avoiding trauma to adjacent tissues that are necessarily in close geometric proximity due to the limited operating space.

10) Arthroscopic Procedures

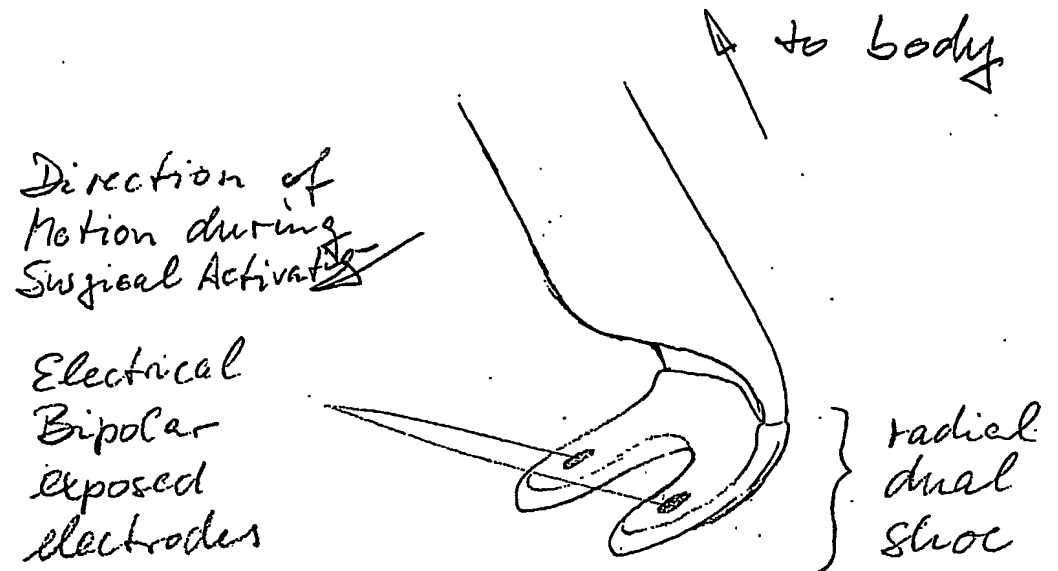
Arthroscopic procedures often involve tissue cutting in a wet field environment. Often it is desired to selectively cut tissue (cartilage, tendon, etc.) from adjoining structures where minimizing the trauma to said adjoining structures (for example, bone) would be desirable to facilitate healing. Also, bleeding obscures the visual field in these procedures. Thus, NeoMedix's selective tissue cutting/coagulation technology could provide the arthroscopic surgeon a superior means for affecting said procedures.

11) Colonoscopy Procedures

Removal of tumors and/or growths or collection of samples for biopsy from the lining of the colon can induce unwanted bleeding and/or unintentional damage to adjacent tissue, such as bowel perforation. NeoMedix's selective tissue cutting/coagulation technology could facilitate cutting of tumors and/or growths or collection of biopsy samples from the walls of the colon by controlling bleeding and protecting against bowel perforation.

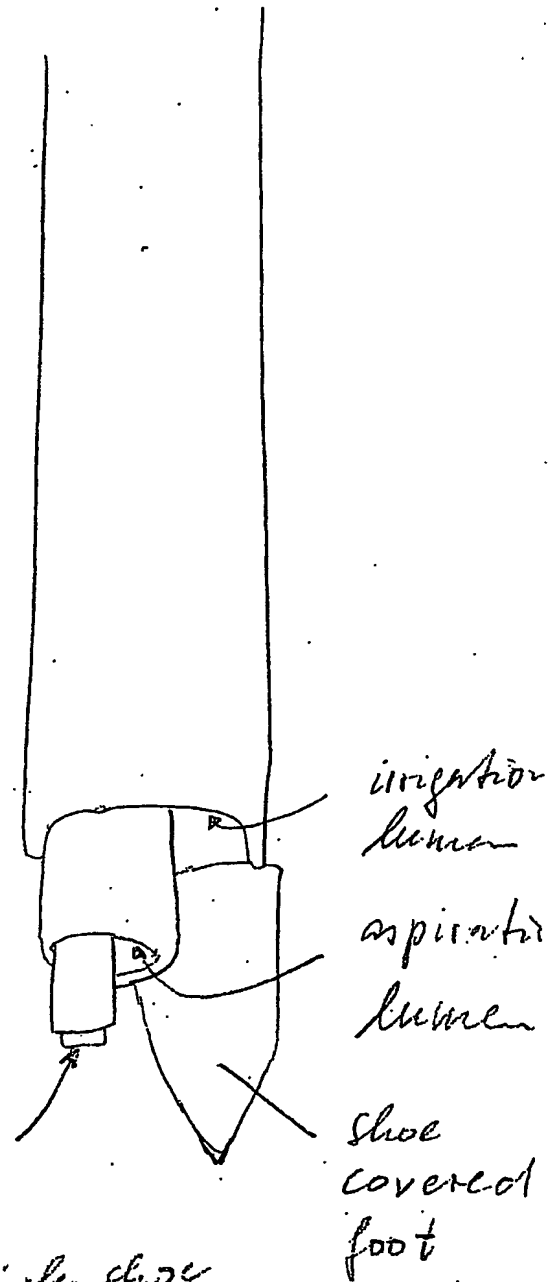


Electrical, Bipolar, radial dual shoe
in cross section

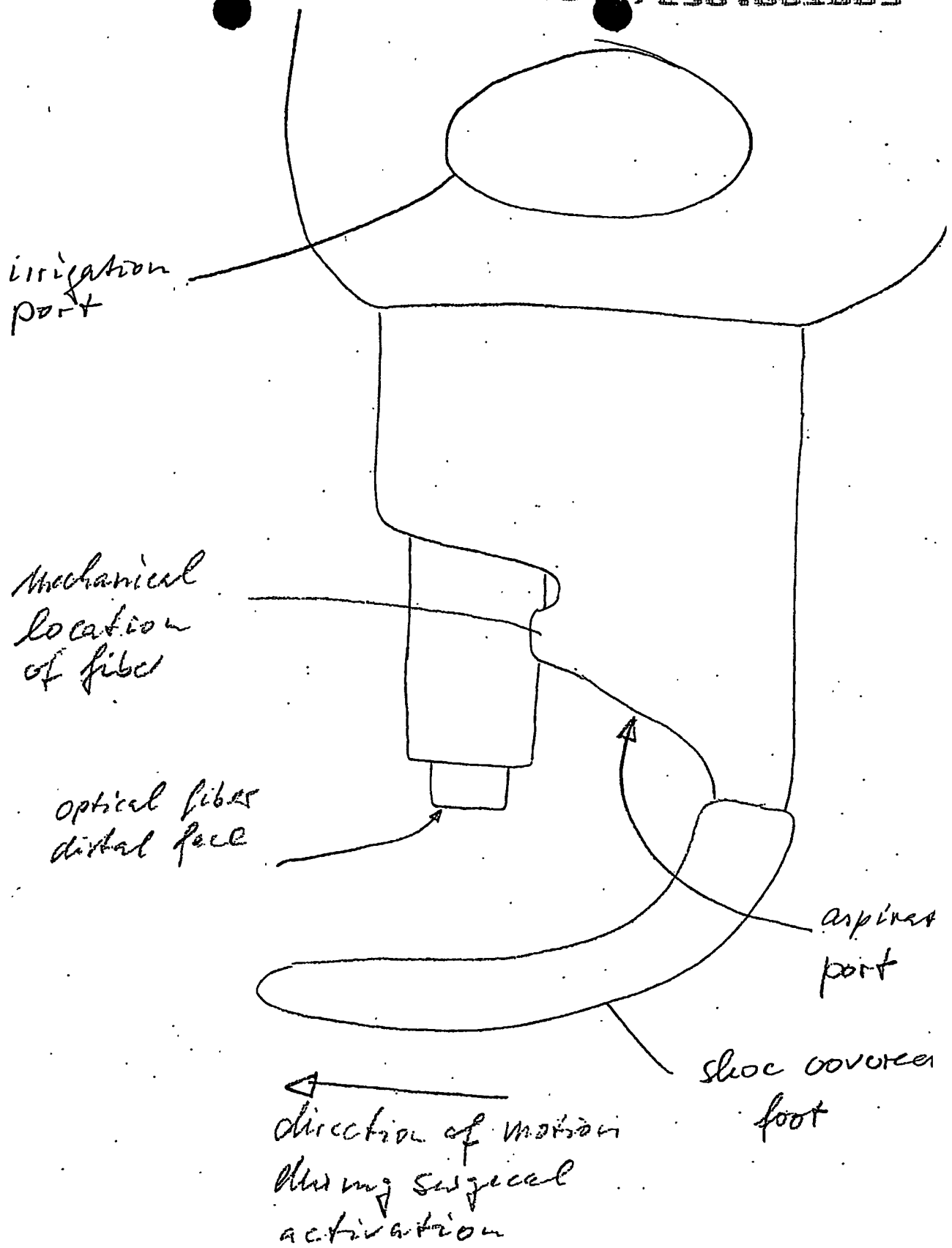


Electrical Bipolar radial dual shoe
blunt forward end

direction of
motion
during
surgical
activation



Electrical monopoles, axial single shoe
with pointed forward end



CONIECTOMY DEVICE

Development History

Disease and Invention

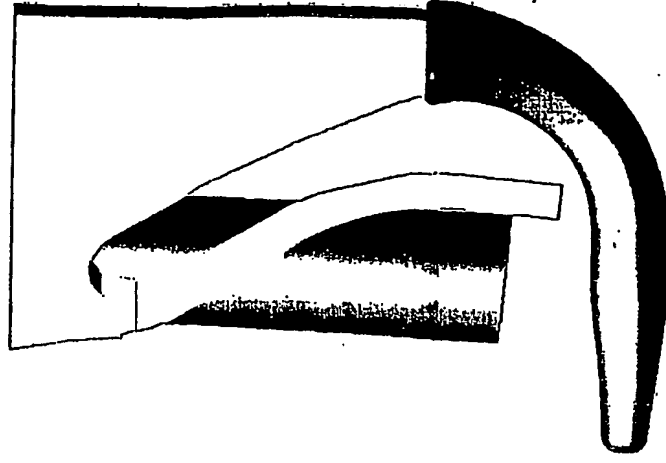
Project Review

Regulatory Plan

Electrosurgical Goniectomy

Alternative Design

1. Two-tube design supports irrigation and aspiration.
2. Electrosurgical cutting means independent of Footplate.
3. Discharge center electrode to Return electrode.
4. Insulated guiding Footplate.



glaucoma history jul 31 02 assem electrodes x1.jpg 0.02"

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CONNECTOMY TECHNOLOGY

Clinical Design Goals

Disease and Invention

Project Review

Regulatory Plan

Handpiece Features:

1. Single-use Disposable Hand-held Instrument.
2. Handpiece connects to a fluid control system consisting of I/A and an electrosurgical generator.
3. Tip designed to enter through 20G MVR blade incision.
4. Insulating material covering the tip to isolate the meshwork from thermal and electrical discharge damage.
5. The meshwork guide footplate angled at 90° relative to the handpiece.

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CONNECTOMY TECHNOLOGY

Clinical Design Goals

Disease and Invention

Project Review

Regulatory Plan

Handpiece Features: (continued)

- o The handpiece body will consist of a 2 white ABS injection molded parts.
- o Insulated electrode wire made from 316V Stainless Steel, ^{or titanium}
- o Insulation shoe material made from polyimide.
- o Full-length Irrigation / Aspiration tubing on the handpiece eliminates tubing connections.
- o Press-on electrosurgical cable connection to the handpiece rear connector.

CONJECTOMY TECHNOLOGY

Ergonomic Considerations

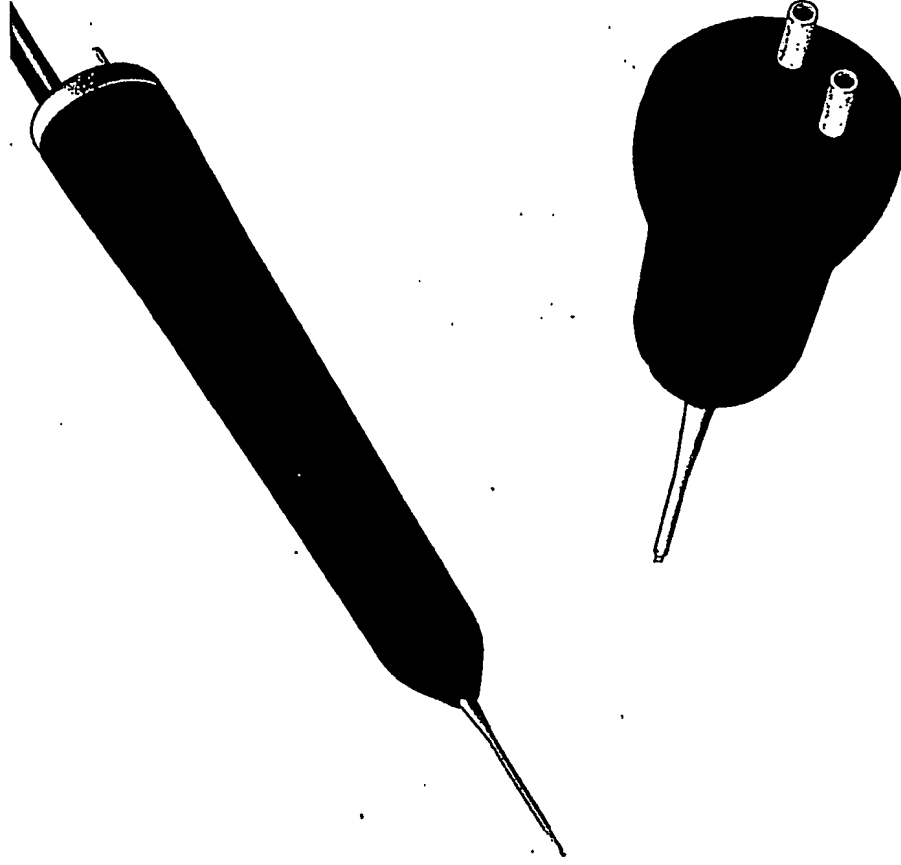
Disease and Invention

Project Review

Regulatory Plan

Ergonomic Challenges:

- o Familiar feel in Surgeon's hand.
- o Short (Vitrectomy Style) vs. Long (Pencil Style)
- o Long (Pencil Style) Approach Selected



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CONNECTOMY TECHNOLOGY

Design for Manufacturability

Disease and Invention

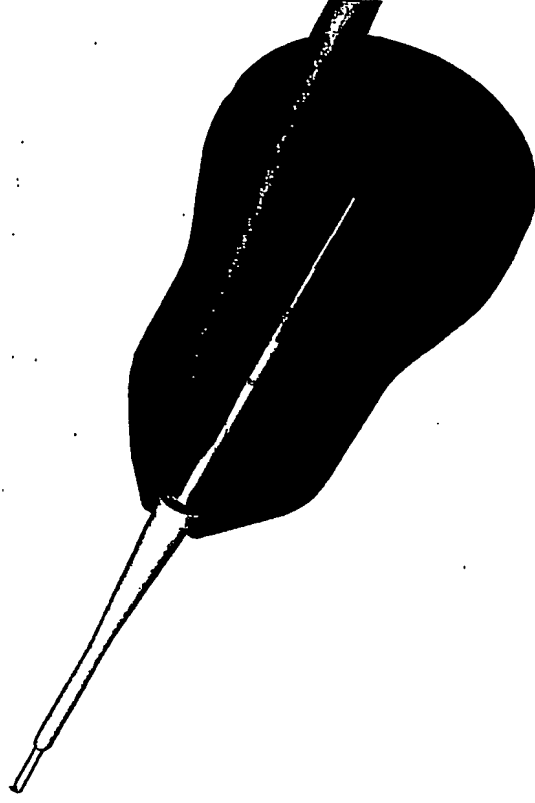
Project Review

.....

Regulatory Plan

Manufacturability Obstacles:

- o Clam Shell Approach Considered.
- o Routing Of Tubes And Wires Problematic.
- o Assembly Challenges Guide Design.
- o Desire To Have Greater Manufacturability.



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CONNECTOMY TECHNOLOGY

Design for Manufacturability

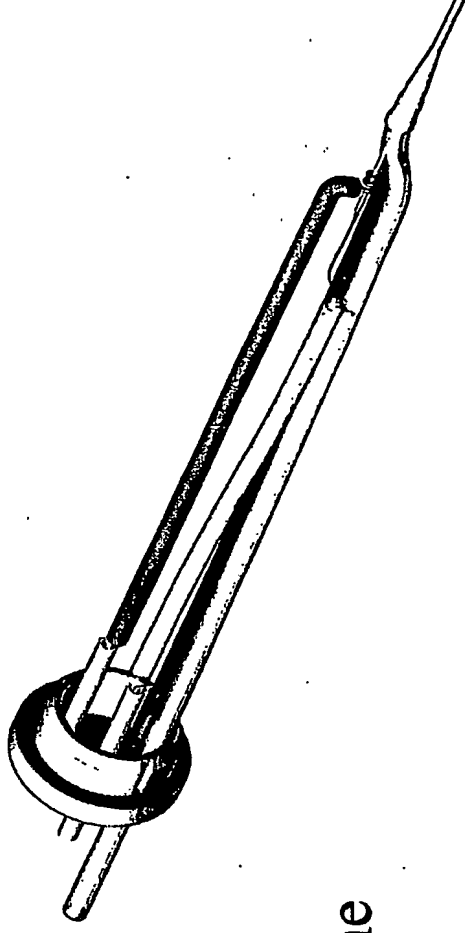
Disease and Invention

Project Review

Regulatory Plan

Manufacturability Obstacles: (continued)

- o Cap Design simple, but Cable Routing Issues Still not solved.
- o Strain Relief Issues Not Addressed.
- o Non-Rigid Assembly, Prone To Damage.
- o Yield issues after final assembly.



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CONNECTOMY TECHNOLOGY

Design Solutions

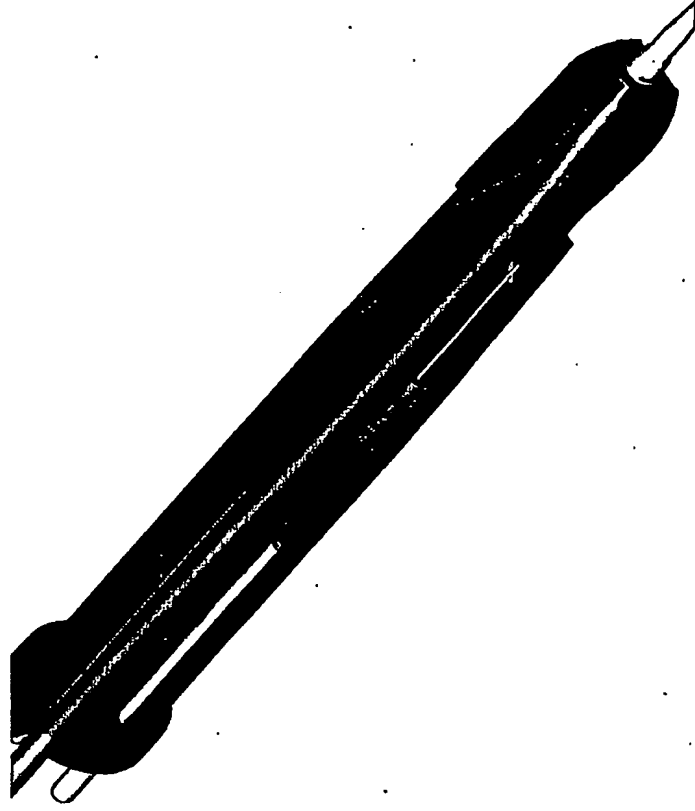
Disease and Invention

Project Review

Regulatory Plan

Solutions to Manufacturability Obstacles:

- o Redesigned Rear Cap to integrate Inner Holder for all working components.
- o Strain Relief Provided for and Axial Repeatability Enhanced.
- o Tubing Paths Supported.
- o More Robust Sub-Assembly for Testing (Rigid Body).



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GONNECTOMY TECHNOLOGY

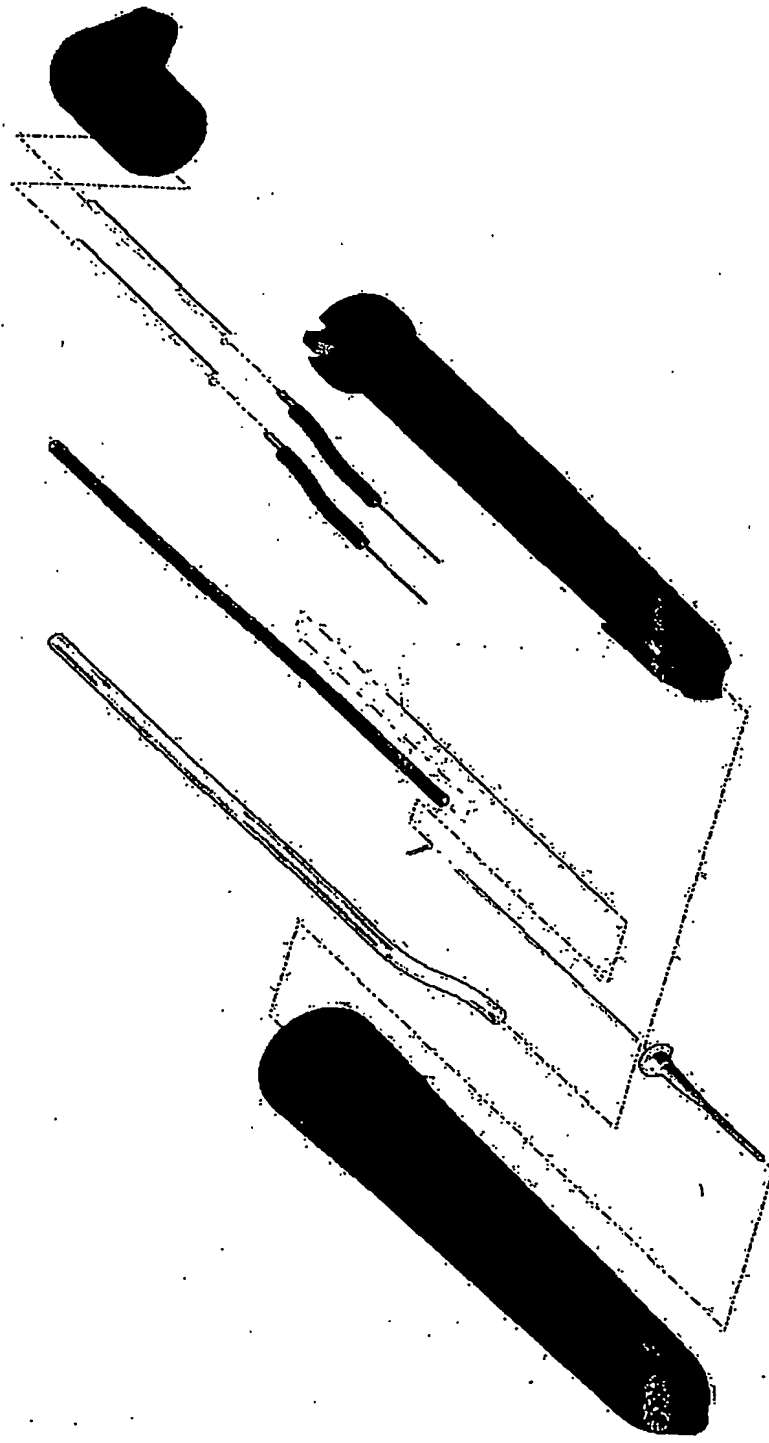
Exploded Assembly

Disease and Invention

Project Review

Regulatory Plan

o Minimization of components.



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CONNECTOMY TECHNOLOGY Handpiece Design Goals Achieved

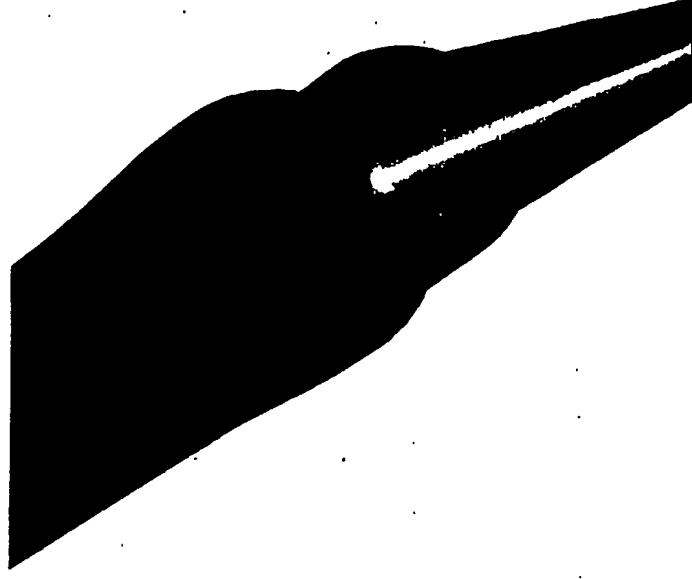
Disease and Invention

Project Review

Regulatory Plan

Design Goals Reached!

- o Push on Bi-Polar Connector fits nearly flush to Handpiece.
- o I/A Tubing are adjacent to the Connector without interference.
- o Surgeon has an ergonomic device to optimize the outcome for the patient
- o Result: Clean, Modular Handpiece Assembly.



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CONNECTOMY TECHNOLOGY

Handpiece Design: Physical Prototype

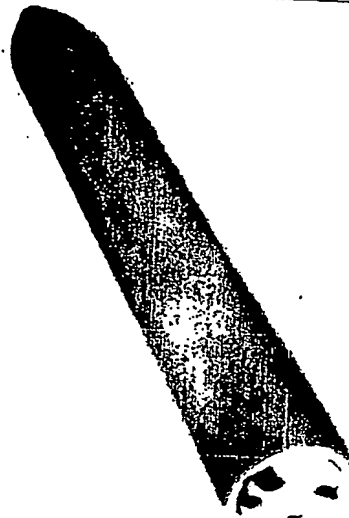
Disease and Invention

Project Review

Regulatory Plan

Handpiece Summary:

- o Met Design Challenges
- o Overcame Issues of Manufacturability.
- o Integrated Surgeon's Feedback.



NEOMEDIX

Purpose: The major resistance to aqueous outflow lies in the trabecular meshwork. Goniectomy is an *ab-interno* surgical procedure, which utilizes a Swan-Jacob goniotomy lens. The goniectome™, a new incisional and ablative device, is advanced across the anterior chamber through a 20g corneal incision. The goniectome™ contains an insulated footplate capable of penetrating the trabecular meshwork into Schlemm's canal. An infusion and aspiration system combined with electroscopy removes a 90° strip of the trabecular meshwork overlying Schlemm's canal. Histology of the angle following this surgery is discussed.

Methods: Human corneal rims preserved in Optisol were sectioned with a goniotomy knife incision and electroscurgical goniectomy and compared with unoperated control.

Results: Control tissue demonstrates a well-preserved normal anatomy of the angle. Goniotomy demonstrates an incision through the trabecular meshwork into Schlemm's canal. Electrosurgical goniectomy demonstrates the absence of a 75-100 μm strip of trabecular meshwork over Schlemm's canal. Moreover both incisional borders of the trabecular meshwork displayed 25-50 μm of coagulative necrosis. Narrowing of the distance between Schwalbe's line and the scleral spur occurs. Descemet's membrane and the corneal endothelial cells appear intact.

Conclusions: Electrosurgical goniectomy is able to remove a full thickness central strip of the trabecular meshwork overlying Schlemm's canal with minimal collateral thermal damage.

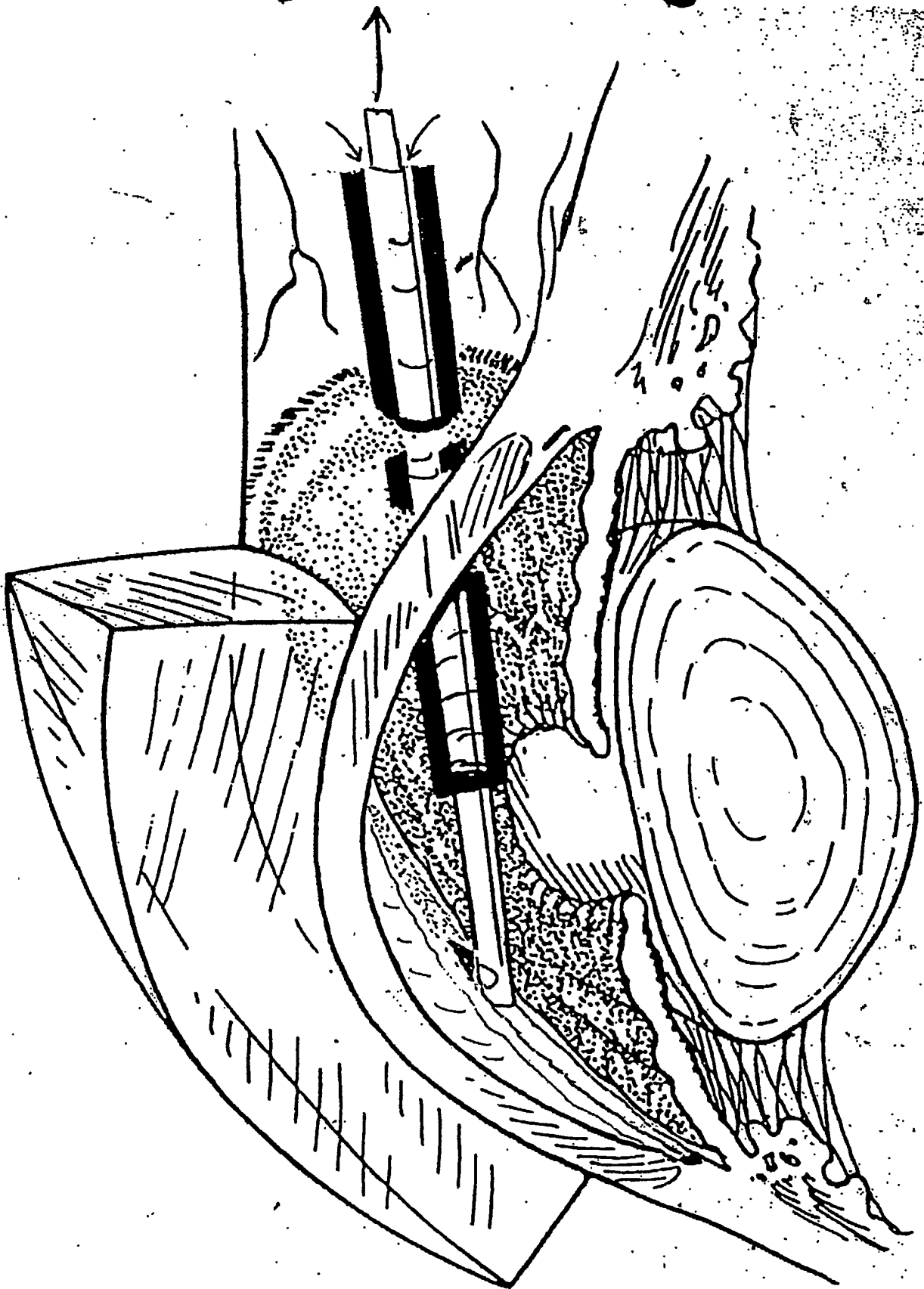
Introduction

Open angle glaucoma's main risk factor is the increase in the IOP. The increase in IOP is due to increased resistance to outflow through trabecular meshwork. The surgical treatment most commonly utilized is filtration surgery that bypasses the trabecular meshwork through a direct opening between the anterior chamber onto the episcleral portion of the globe. Such filtration surgeries include trabeculectomies, non-penetrating trabeculectomies, and glaucoma implants.

The first surgery directed at the trabecular meshwork was introduced in 1938 with the description of the technique of goniotomy. The principal was to perform an ab-interno surgery cutting the trabecular meshwork so that fluid would flow into Schlemm's canal.

The width of Schlemm's canal is 250 to 300 micrometers with a length of 36 mm. The 30 collector channels leave Schlemm's canal sending fluid through the sclera to the aqueous veins and the scleral venous complex. In 1942, the success rate of goniotomy was first published since that time it has achieved a 90% success rate with no medications in congenital glaucoma. IOP in these patients are usually maintained throughout life at between 10 to 14 mm Hg.

Goniotomy has been utilized with minimal success in POAG. There have been recent articles describing a good success rate with this surgical procedure. There have been a number of attempts of ab-interno surgical procedures such as lasers, trabecular ablation, goniocurettage, and trabecular bypass with a stent in Schlemm's canal for POAG.



Proposed Technique of Ab-interno Goniectomy

Surgery for Open Angle Glaucoma

The proposed surgery is based on the elegant goniotomy surgical technique. A Swan-Jacob goniotomy lens is required. A 20-gauge temporal clear cornea incision is made with a MVR blade. The goniectome™ is introduced and a 90° section of the pigmented trabecular meshwork is ablated. The instrument is removed from the eye and the corneal wound is sealed by hydration.

Goniectomy System

a). **External system:** A mobile stand with gravity fed bottle for the infusion, and an automated aspiration device with a separate cautery control. A surgeon controlled 3-stage foot switch for infusion, aspiration, and ablation is used.

b). **Intraocular Instrument-goniectome™**: The goniectome™ consists of a handle with separate 20-gauge infusion and 25-gauge aspiration ports and coupling for the cautery. The 25-gauge shaft is 5 mm longer than the infusion shaft. The distal end of the 25-gauge aspiration system is bent 90° to the shaft to create the footplate. The footplate consists of a sharp point to penetrate the trabecular meshwork into Schlemm's canal. The footplate is insulated with polyamide to prevent heat dissipation. The footplate and insulation prevent heat from reaching the scleral portion of Schlemm's canal that could damage the endothelial cells and the collector channels. Once the footplate is in Schlemm's canal it acts as a guide along the scleral groove and feeds tissue to the ablative device. The ablative device is housed at the base of the 25-gauge shaft leaving a space of 150 mm between the cautery elements and the footplate.

Histological Studies

Fresh human cornea scleral rims, preserved in Optisol that had been used for penetrating keratoplasty, were utilized for the histological studies. 90° sections of the rims were sent for either a control, ripping by the goniectome™ utilizing no aspiration or cautery, goniotomy knife incision or goniotomy surgery. Different cautery settings were used to assess the tissue effects. All surgical maneuvers were performed under an operating microscope with the cornea scleral tissue suctioned onto a device especially built for this maneuver. All surgical procedures were performed under balanced salt, which filled the holder.

Histology of the control tissue demonstrated that the angle structures were well preserved.

Histology of the tearing technique demonstrated that the trabecular meshwork was dehist from Schwalbe's line on all specimens leaving the rest of the trabecular meshwork intact.

Goniotomy specimens were either cut half to three-quarters way through the trabecular meshwork or the goniotomy knife incision could be seen on the scleral portion of Schlemm's canal penetrating into the scleral lamellae.

This histology of the prototype goniotome™ demonstrates the removal of a 150 to 250 micron strip of the trabecular meshwork overlying Schlemm's canal. There was minimal thermal coagulation found in the adjacent trabecular meshwork. There appears to be a decrease in the endothelial cell density on the scleral portion of Schlemm's canal. In no specimen was Descemet's membrane dehist.

Conclusion

The goniotomy system using prototype hand pieces ablates the middle 1/3 of the trabecular meshwork overlying Schlemm's canal with minimal collateral damage.

References:

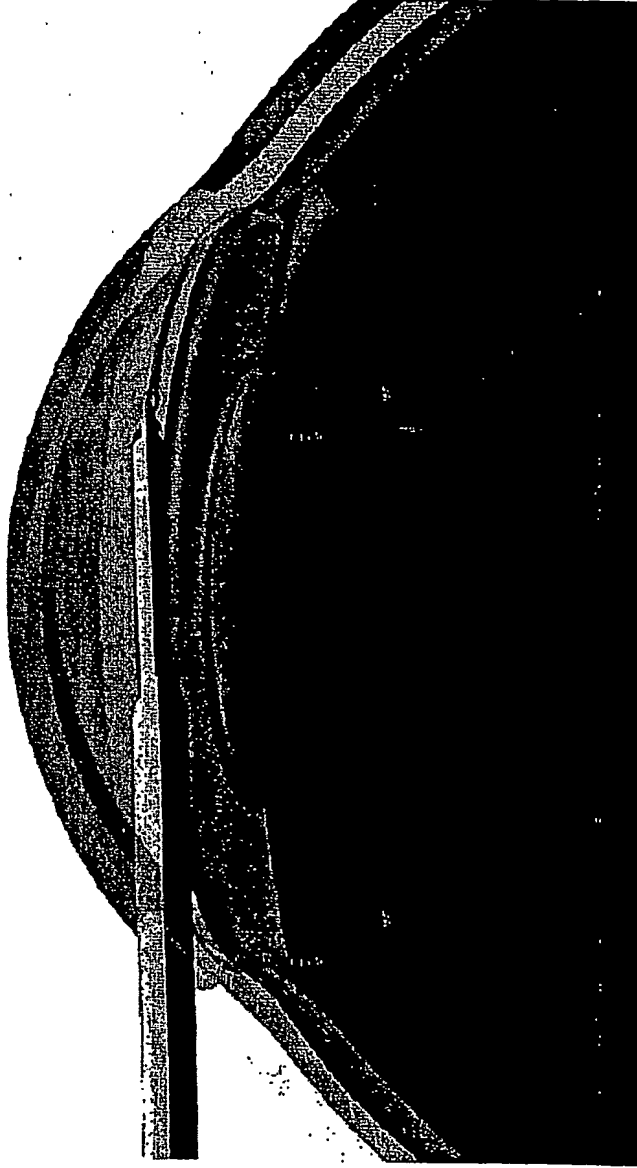
- Quaranta L, Hitchings RA, FRCOph, Quaranta CA. A-Interno goniotrabeculectomy vs. Mitomycin C trabeculectomy for adult open-angle glaucoma. *Ophthalmology*: 106:7 1999, 1357-1362.
- Dietlein TS, Luke C, Jacobi PC, Frieglstien G. Individual factors influencing trabecular morphology in glaucoma patients undergoing filtration surgery. *Journal of Glaucoma*. 11: 03,2002, 197-202.
- Freedman SF, Rodriguez-Rosa RE, Rojas MC, Enyedi LB. Goniotomy for Glaucoma secondary to chronic childhood uveitis. *American Journal of Glaucoma* 133:5; 2002, 617-621.
- Jacobi PC, Dietlan TS, Krieglstein GK. Microendoscopic trabecular surgery in glaucoma management. *Ophthalmology*: 106:3 1999 538-544.

Ab Interno Goniotomy for POAG

- 20 g temporal corneal incision
- Goniotome™ instrument
- Swan-Jacob's gonio lens
- 90-120 removal of middle 1/3 TM
- Hydrate cornea

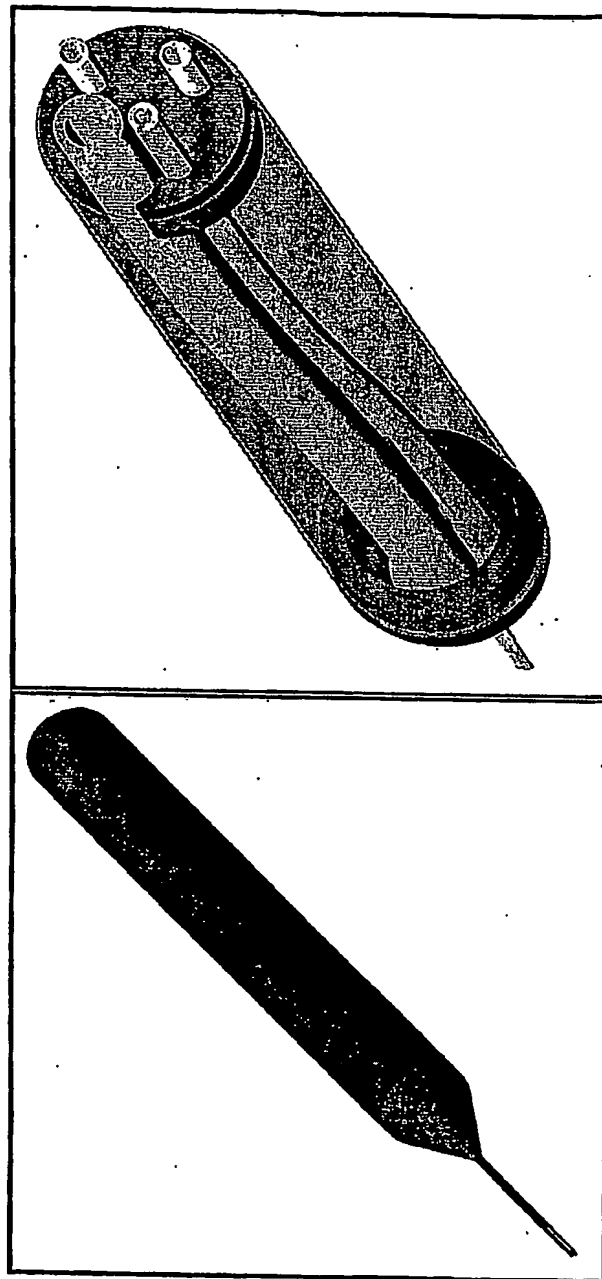
Ab Interno Goniotome™ System for POAG

Removes the middle 1/3 of the trabecular meshwork in a highly atraumatic fashion



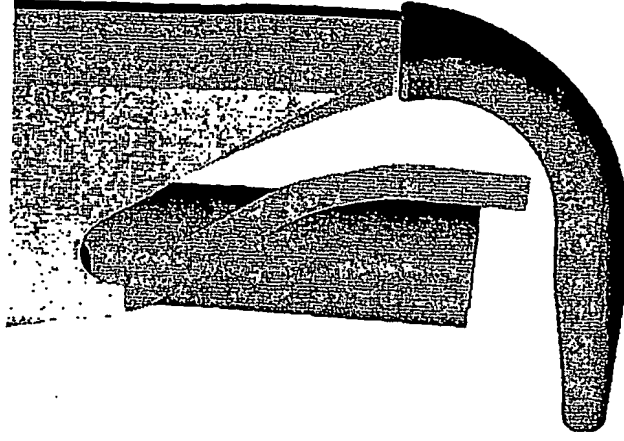
Goniectome™ Device for POAG

*Goniectomy with Cautey
Integration into Handpiece*



Goniectome™ Device for POAG

1. Irrigation
2. Aspiration
3. Cautery for cutting
4. Insulated Footplate

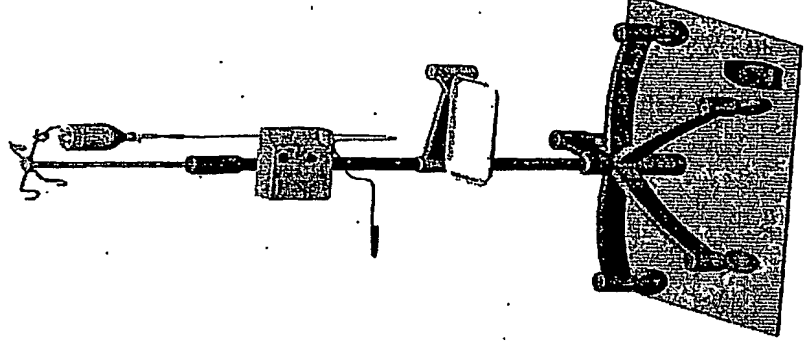


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Gonectome™ Technology Integrated Console

Integrated Console :

- Fluid Flow Control
- Irrigation
- Aspiration
- Cautery

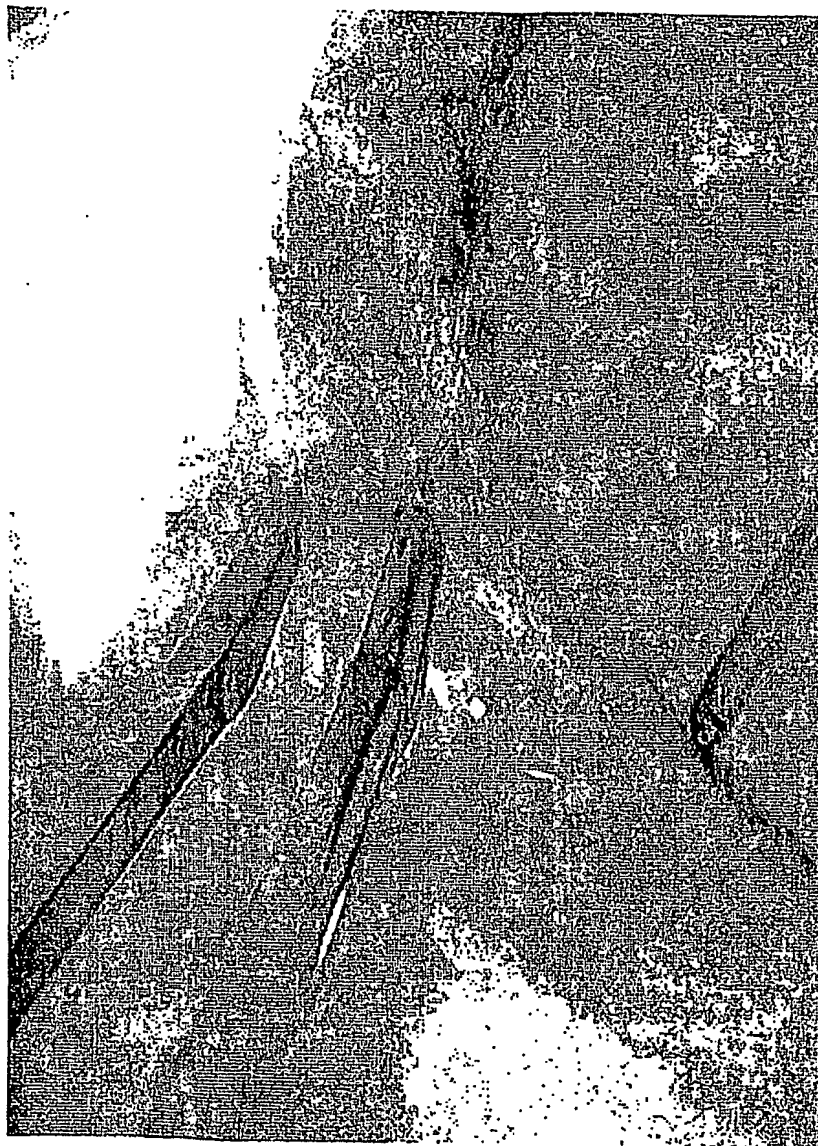


Goniectome™ Studies

- Custom designed holder
- Corneo-Scleral rim suction
- Performed under BSS
- Operating microscope
- Direct view of trabecular meshwork

Goniectomy System for POAG

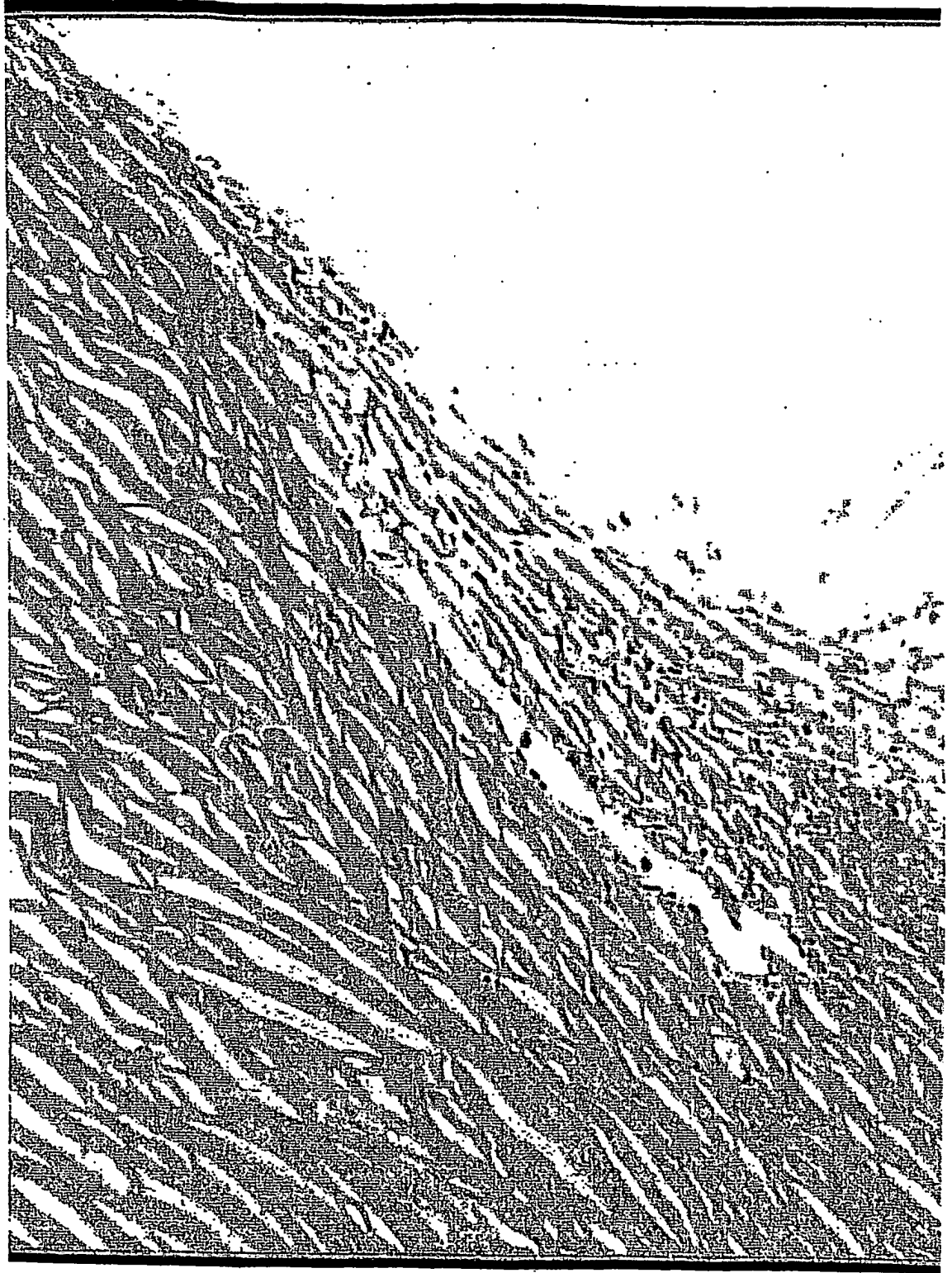
Human Corneal Trabecular Meshwork Removal



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Control

Angle structures are well preserved



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Tearing

TM dehist from Schwalbe's line on all specimens



Goniotome

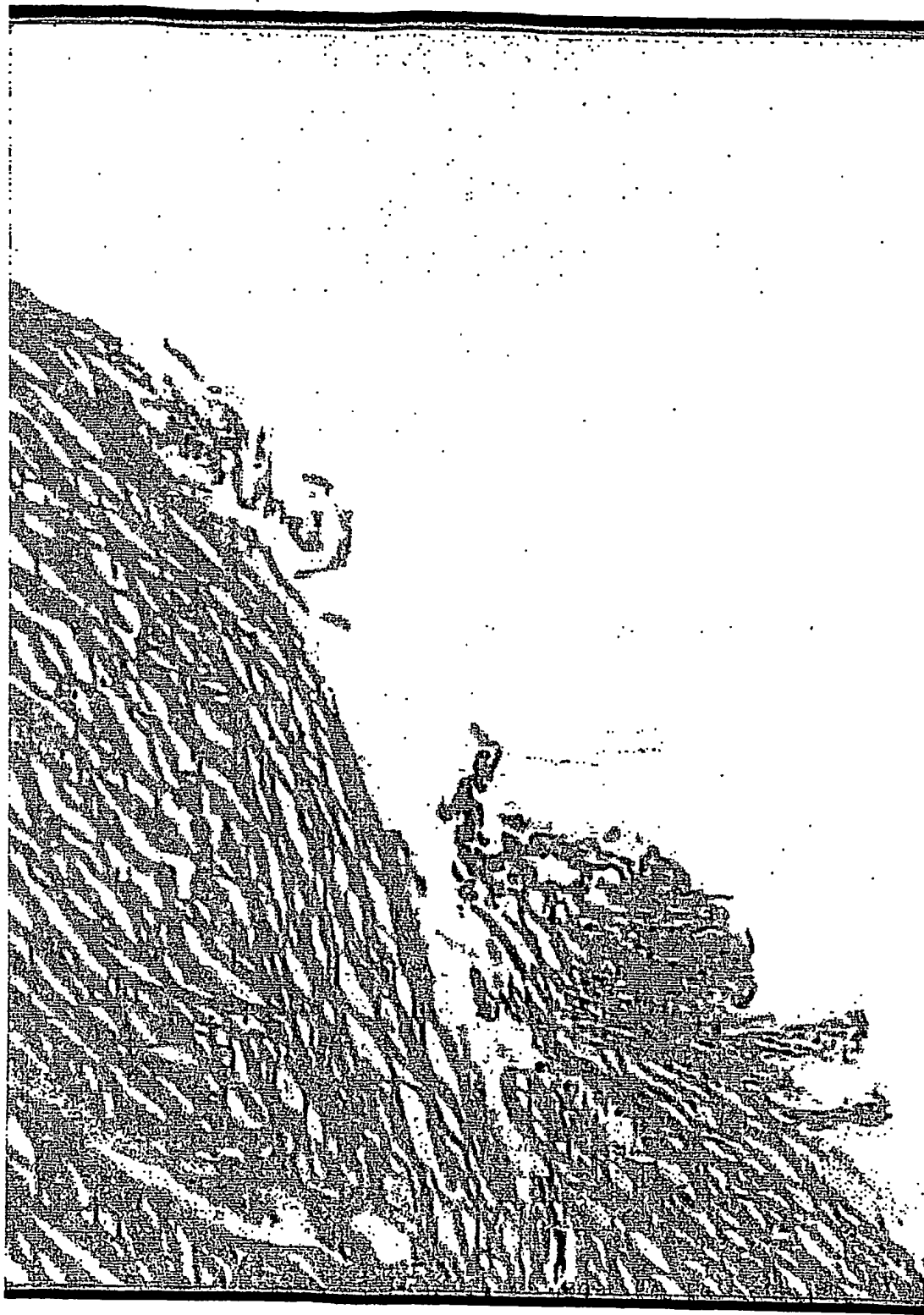
Incision penetrates into the scleral lamellae



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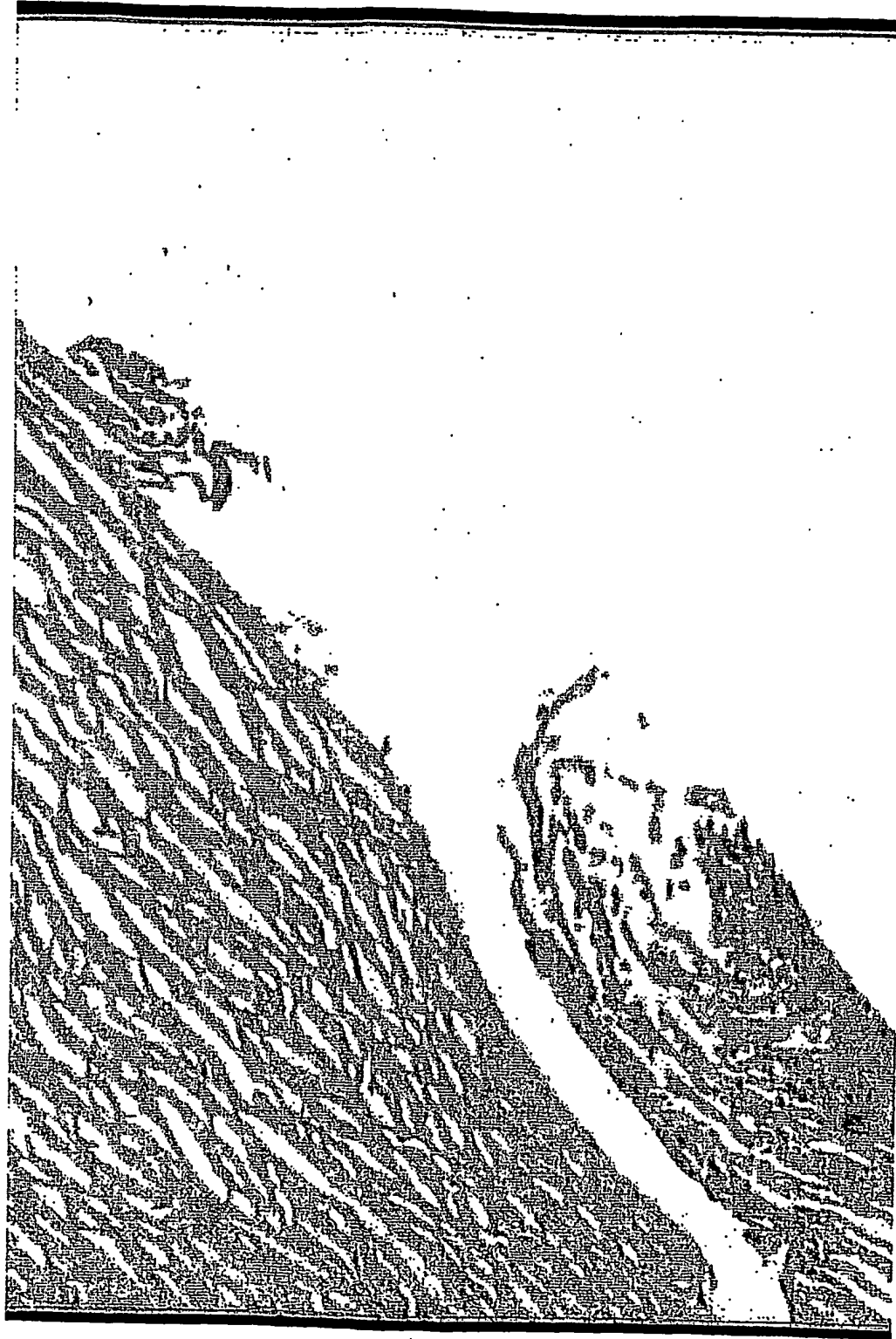
Goniectome™ 0.3 Watts

Removal of a 150 to 250 micron strip of the TM
overlying the Sclemm's canal



Goniectome™ 0.7 Watts

Removal of a 150 to 250 micron strip of the TM
overlying the Sclemm's canal



Conclusion

- Minimally invasive POAG surgery
- Integrated goniotomy system
- Opening Schlemm's canal into the AC
- Histology demonstrates reasonably acceptable thermal collateral damage
- Effect on collector channels ?
- The proof of the pudding is in the eating thereof

GONIECTOMY

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R. S. Chuck MD/PhD, UC Irvine

R.F. See MD, USC Doheny Eye Institute

N. Rao MD, USC Doheny Eye Institute

GONIECTOMY

U.S. Patent Application 10/052,473

PTC Patent Application US 02/01665

UC Regents

Inventors – G. Baerveldt & R. S. Chuck

Consultant – NeoMedix Corp.

Development/Manufacture – NeoMedix Corp.

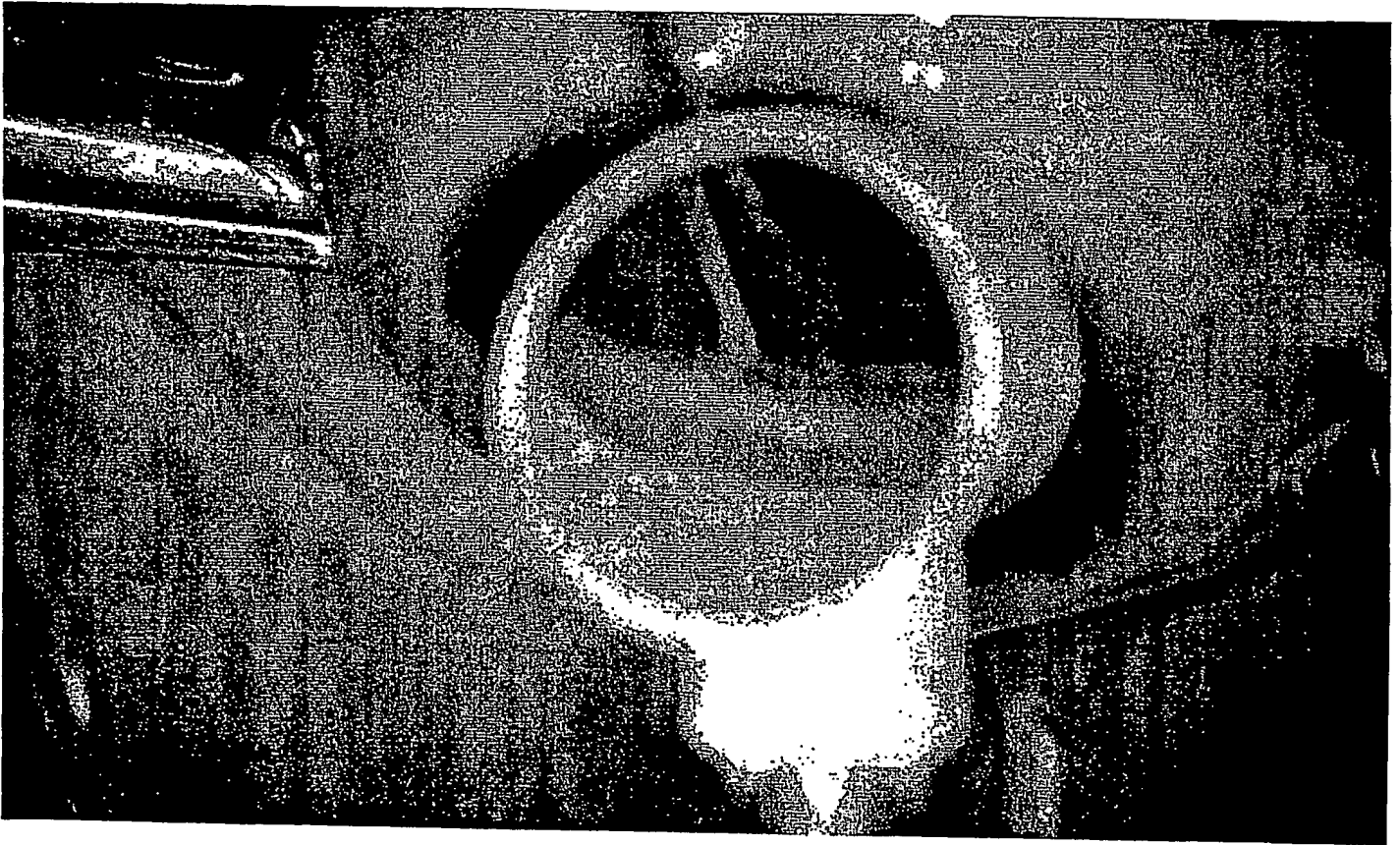
TRABECULAR MESHWORK SURGERY

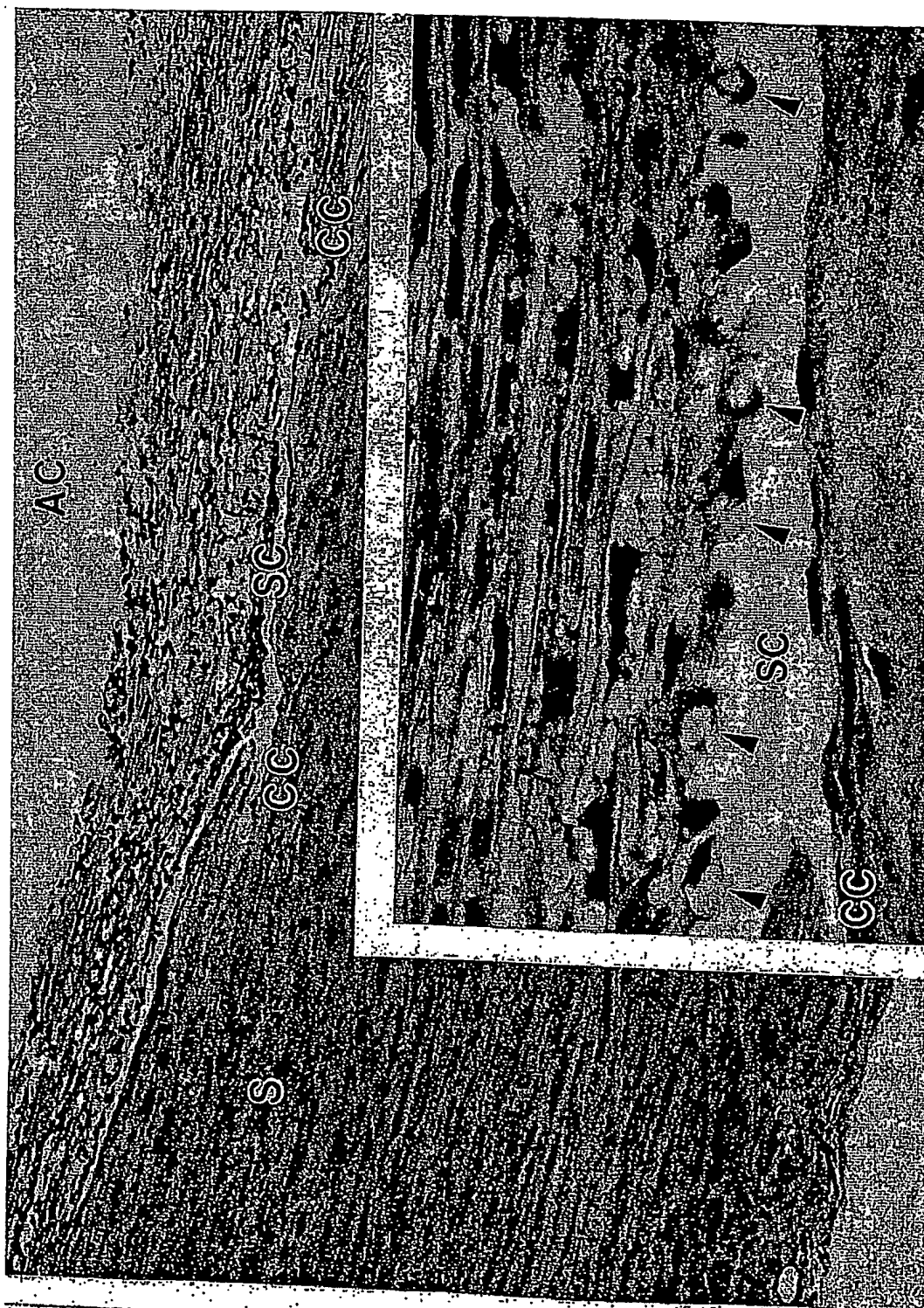
- Goniotomy
- Trabeculotomy
- Goniocurrettage
- Trabecular ablation - Er. YAG
- Non-penetrating trabeculectomy

Goniotomy

- 1938 Barkan Goniotomy Technique
- 1942 Barkan Success Rate
- Tissue Elasticity & CB Muscle Insertion in Congenital Glaucoma

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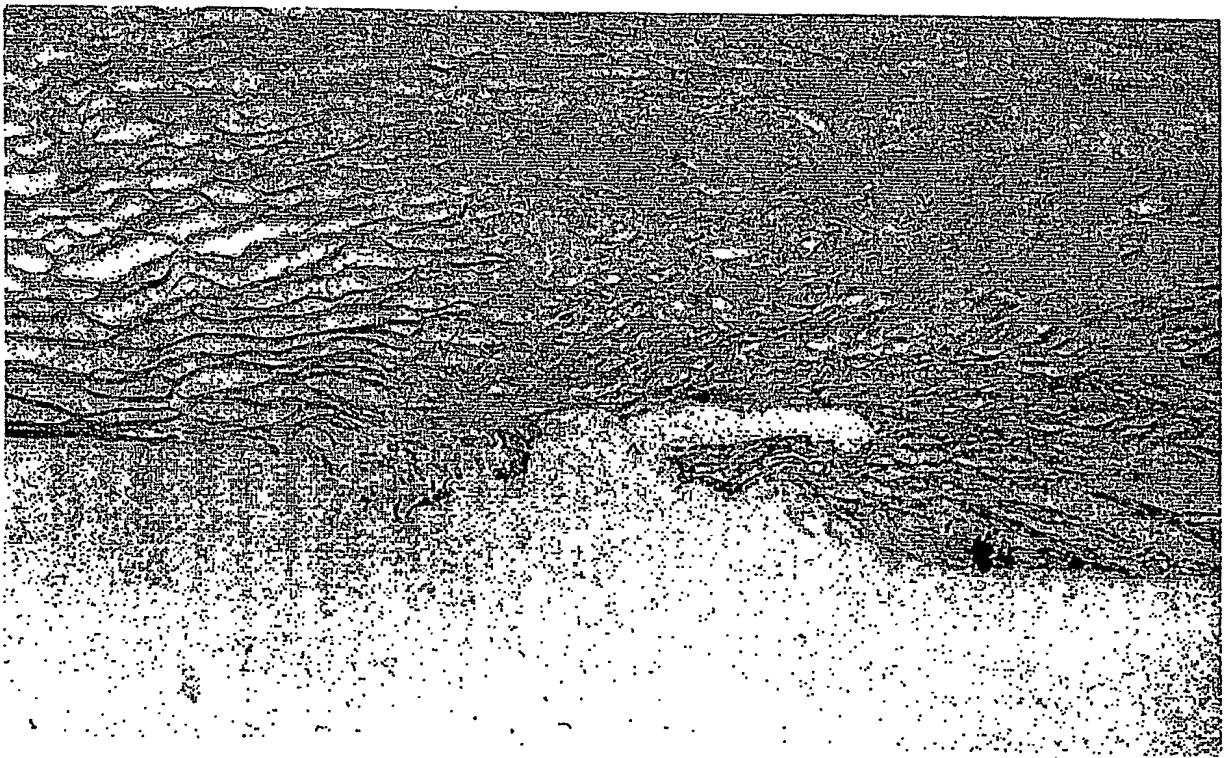




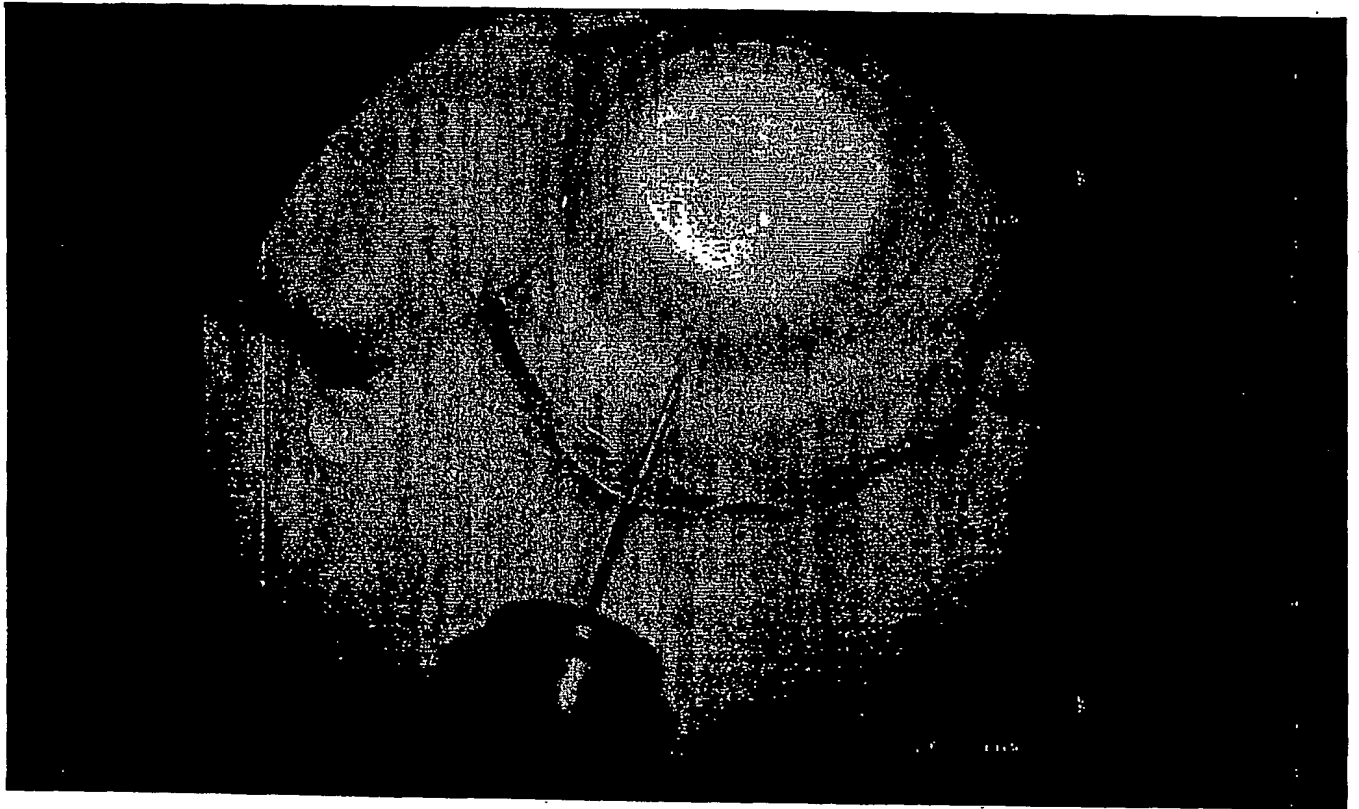
Schlemm's Canal

- Width 250-350 microns
- Length 36 mm+/-
- Collector Channels 30+/-

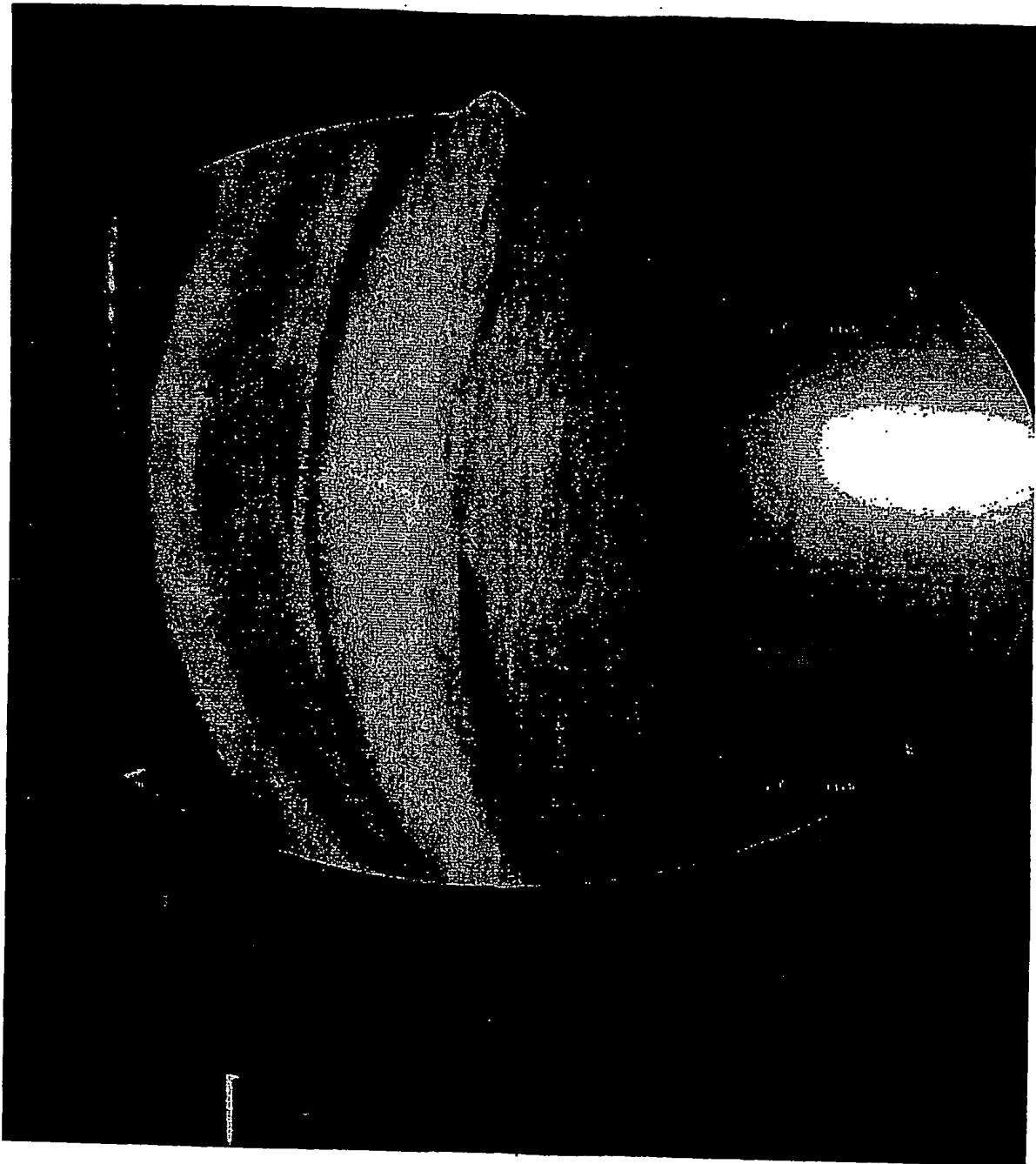
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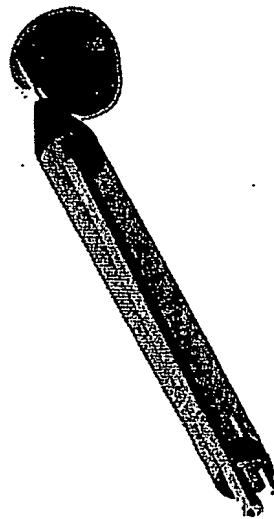


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Goniectomy System

Completed by opening and removing a strip of the trabecular meshwork in a highly atraumatic fashion.



GONIECTOMY SURGERY

MVR Corneal Incision - 20g

Goniectomy Instrument - Infusion

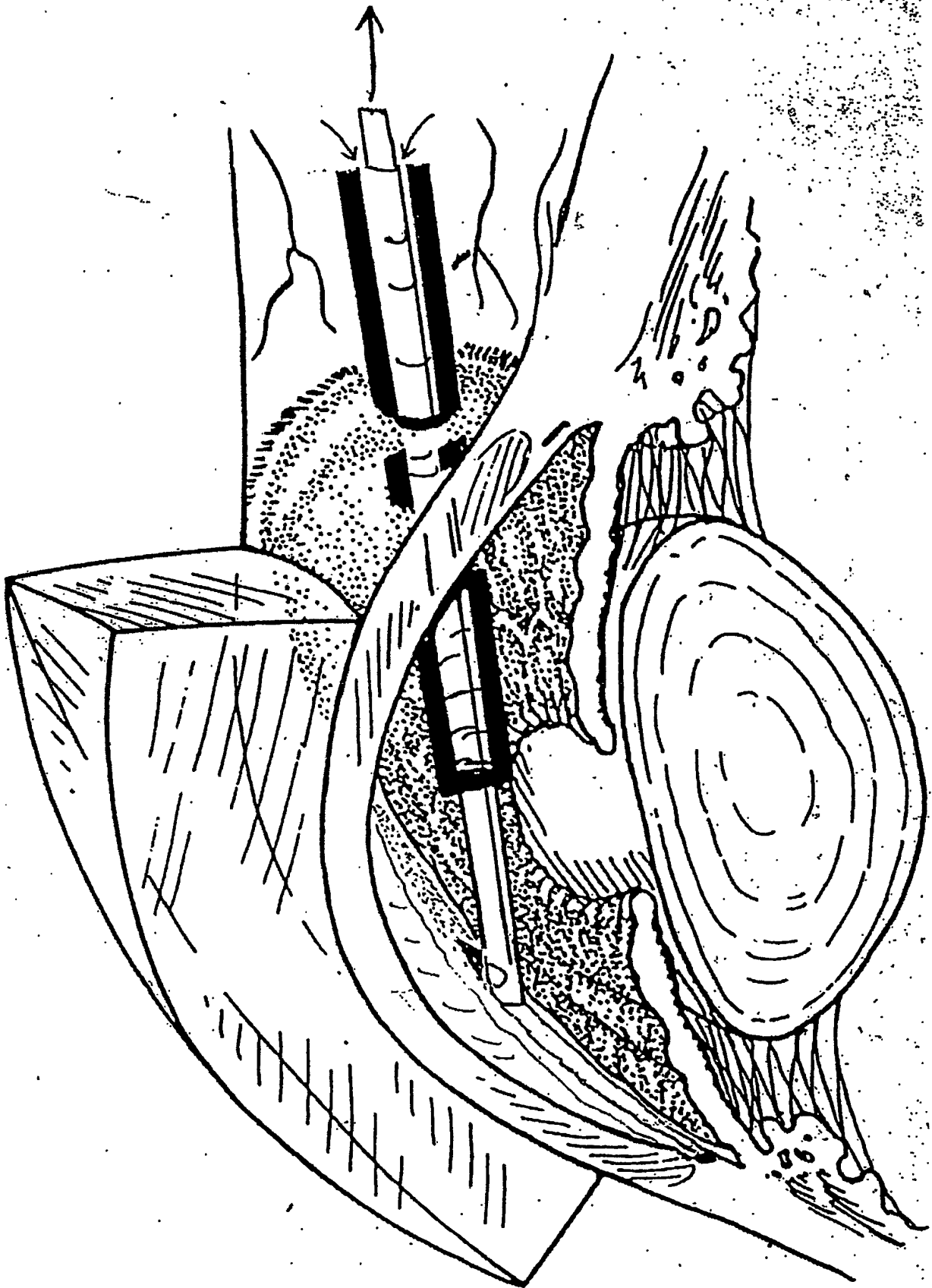
Penetrate Trabecular Meshwork

Remove 90° Trabecular Meshwork

Hydrate Cornea

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CONNECTOMY INSTRUMENTS

Tissue Removal

Mechanical

Vitrector, 25 gauge

Thermal

Cautery

Vaporization

Laser

Fragmentation

Sonic or Ultrasonic Energy

INFUSION / ASPIRATION

FOOTPLATE Protection of Collector Channels

Penetrate Trabecular Meshwork

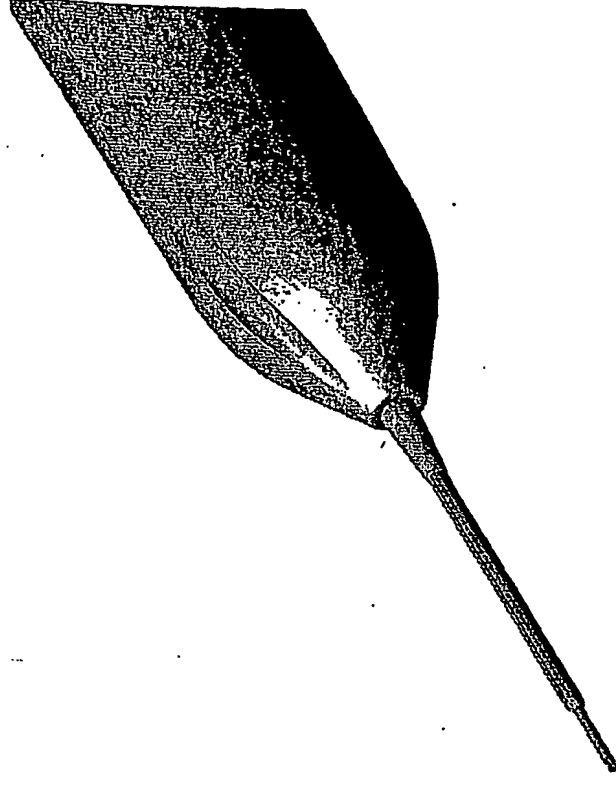
Guide in Schlemm's Canal

Feeds Into Tissue Removal System

GONIECTOMY DEVICE

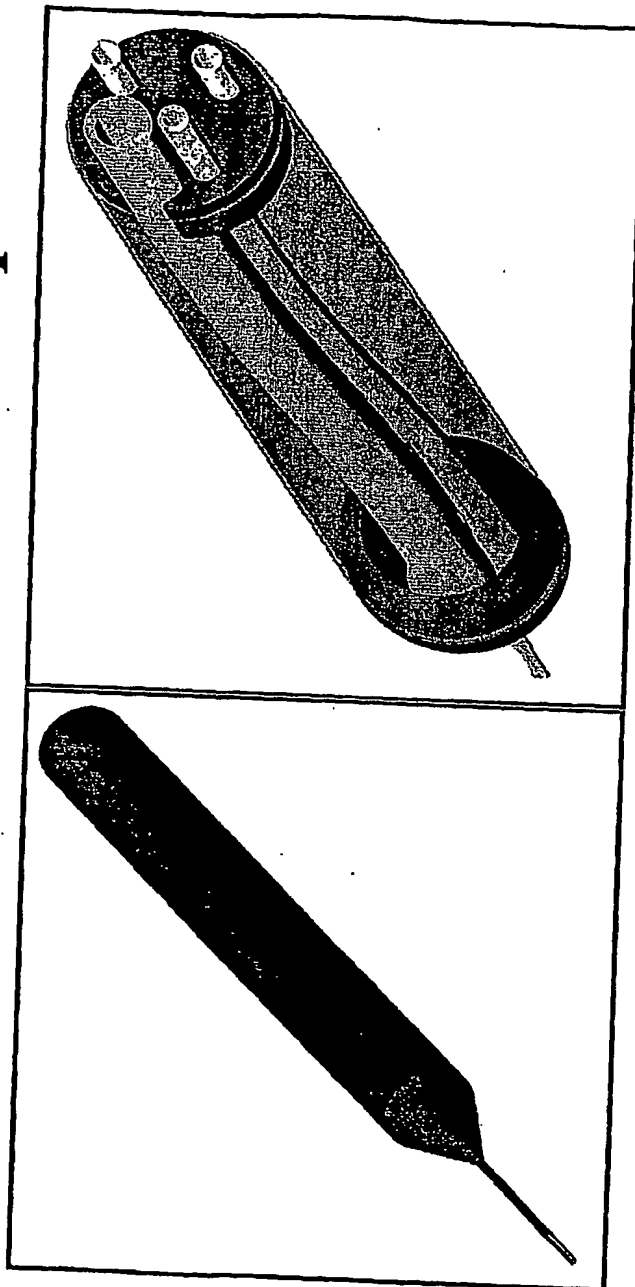
Development History

1. Three-tube design elements:
irrigation, aspiration, energy
delivery.
2. Footplate provides a guide
and protection of SC.
3. Choice of Multiple Forms of
Energy



GONIECTOMY DEVICE Development History

Electrosurgical Goniectomy
Concept: Integration into Handpiece



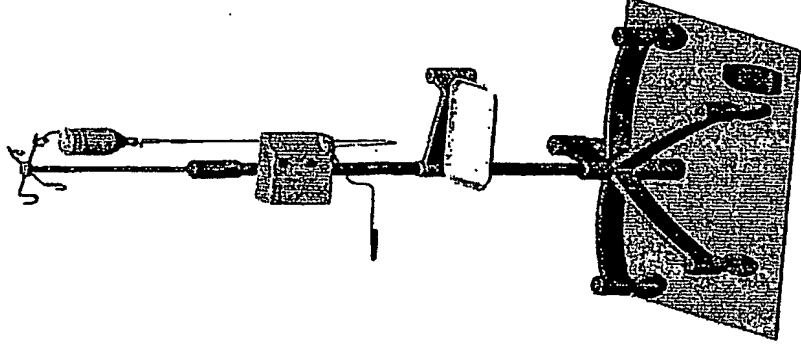
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GONIECTOMY TECHNOLOGY

Integrated Control System

Integrated Console :

- Fluid Flow Control
- Irrigation
- Aspiration (Syringe)
- Electrosurgical Power



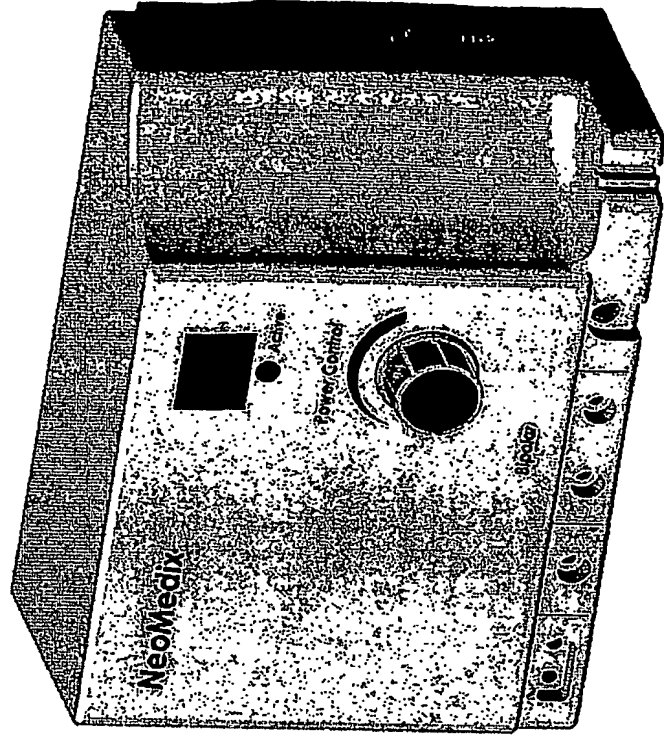
GONIECTOMY TECHNOLOGY

Integrated Control System

Console Integration Elements:

Electrosurgical Sub-System

- FDA and European regulatory approved.
- Bipolar and monopolar capable
- Adjustable bipolar power levels from 0.1 to 30W
- Remote foot pedal control



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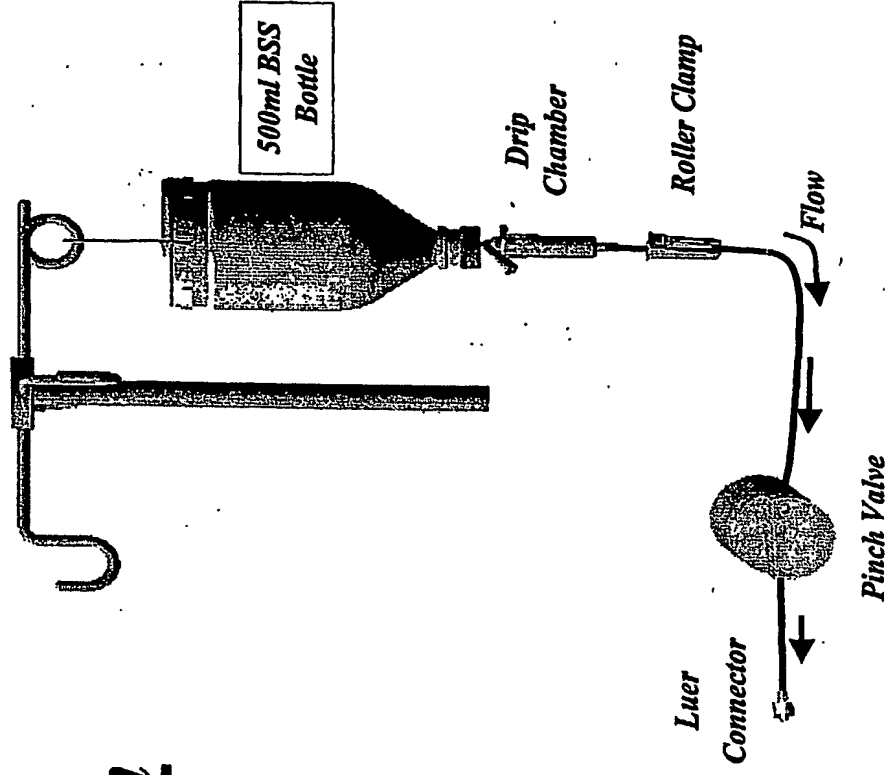
GONIECTOMY TECHNOLOGY

Integrated Control System

Console Integration:

Irrigation Sub-System

- Gravity fed irrigation of standard 500ml BSS bottle
- Adjustable bottle pole height
- Normally open pinch valve for safety
- Disconnect fitting allows for handpiece exchange

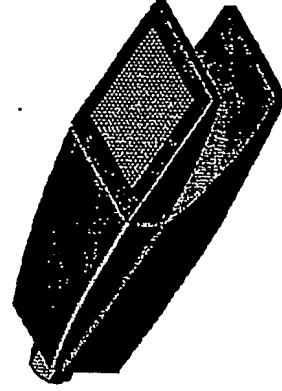


GONIECTOMY

Integrated Control System

Footpedal control system

<i>Footpedal</i>	<i>Function</i>
Region 0	OFF
Region 1	Infusion
Region 2	plus Aspiration
Region 3	plus Electrosurgical

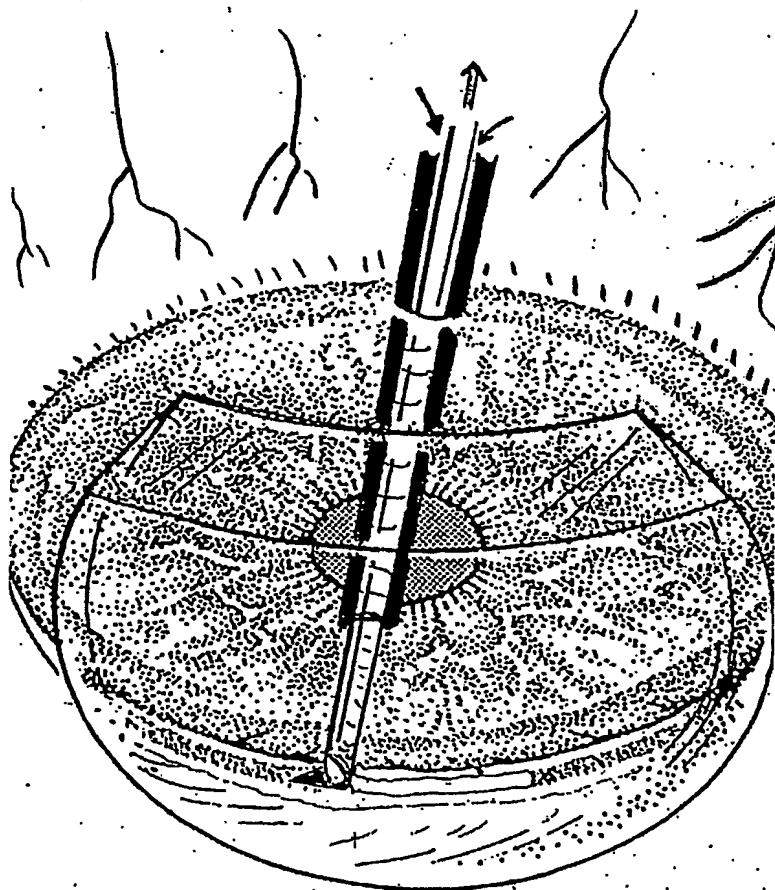


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Goniotomy System

25 Gauge Shaft

Aspiration, Caутery, Footplate



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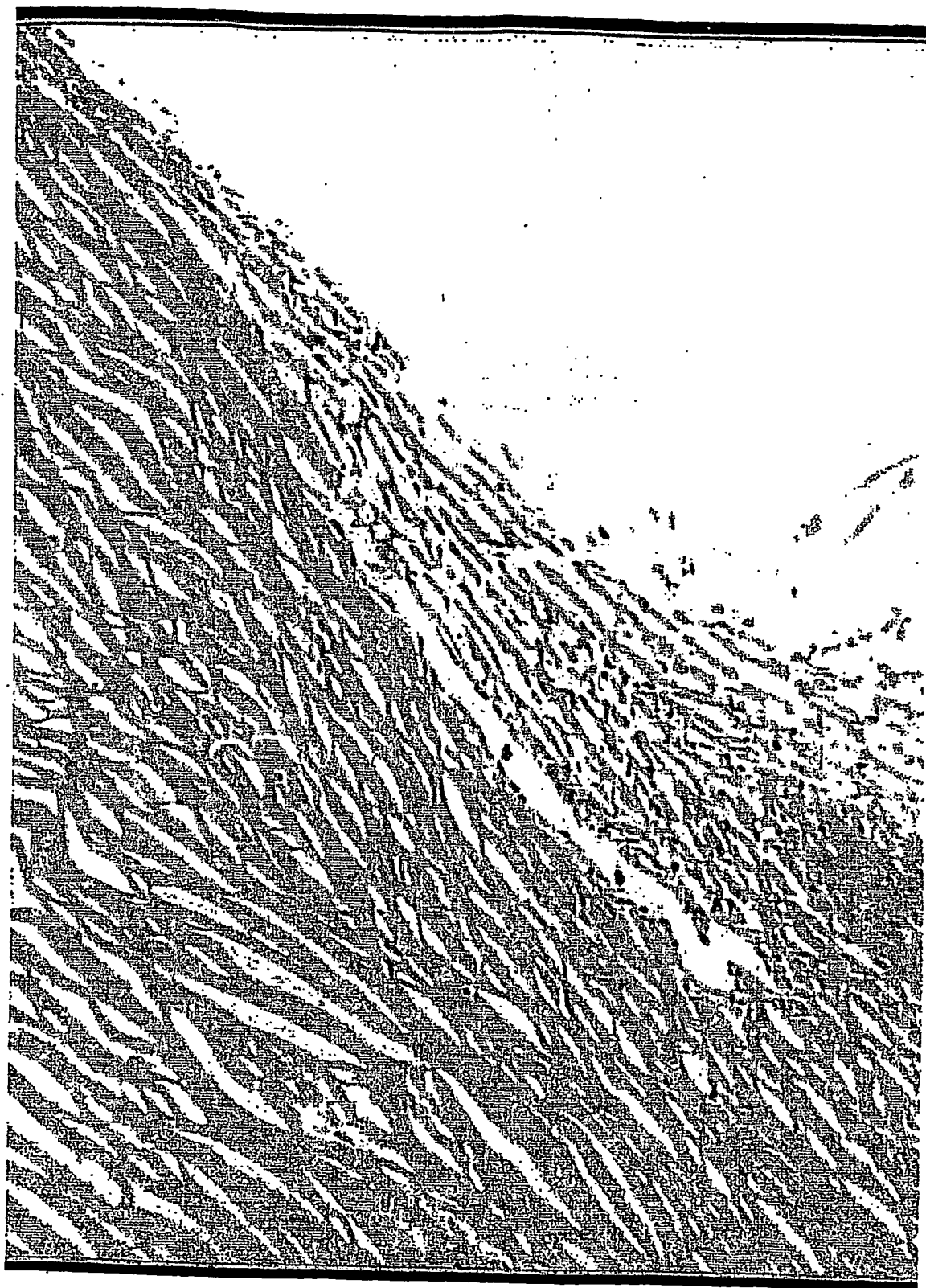
Goniectomy System

Human Corneal Trabecular Meshwork Removal



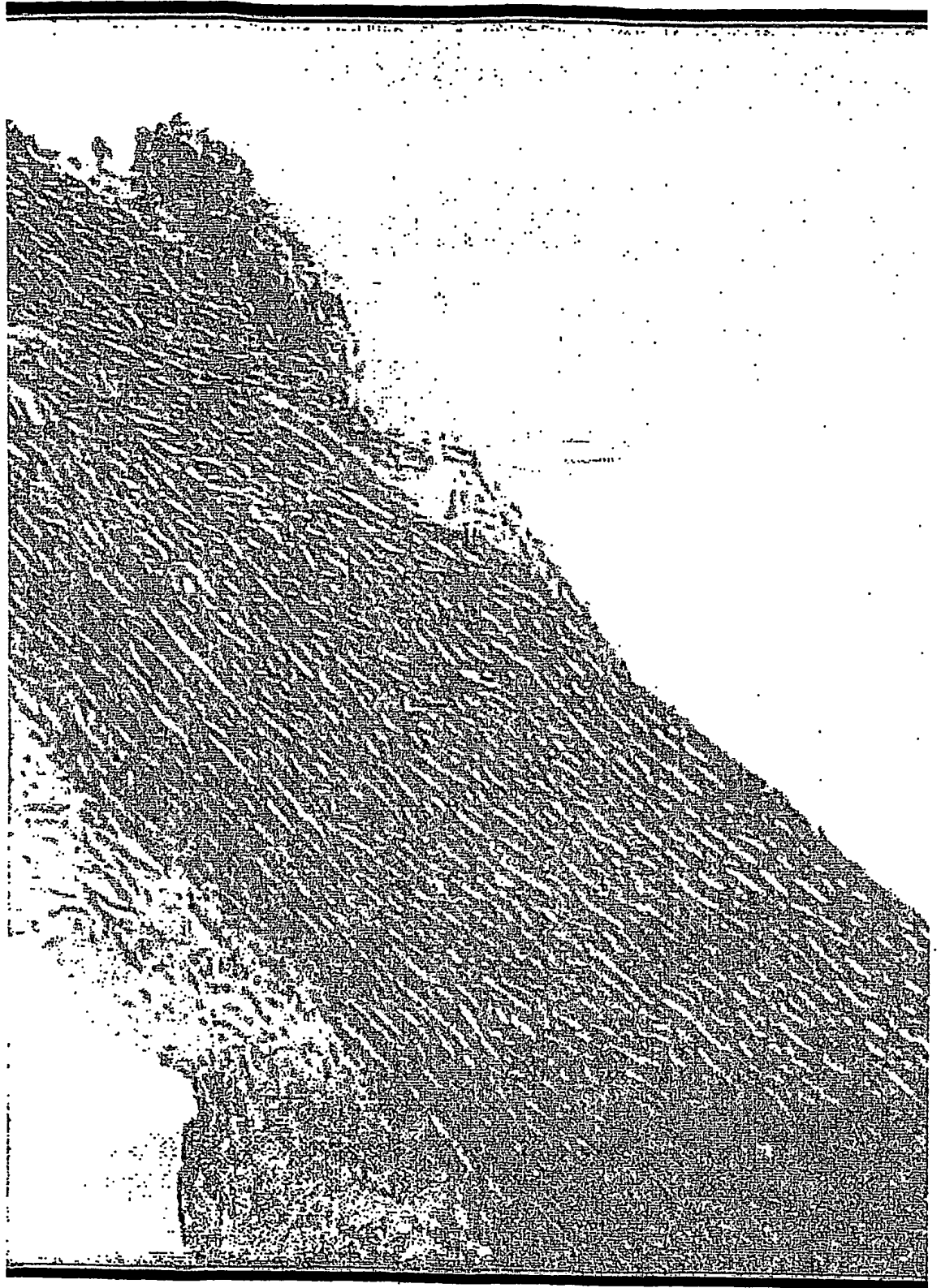
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Control



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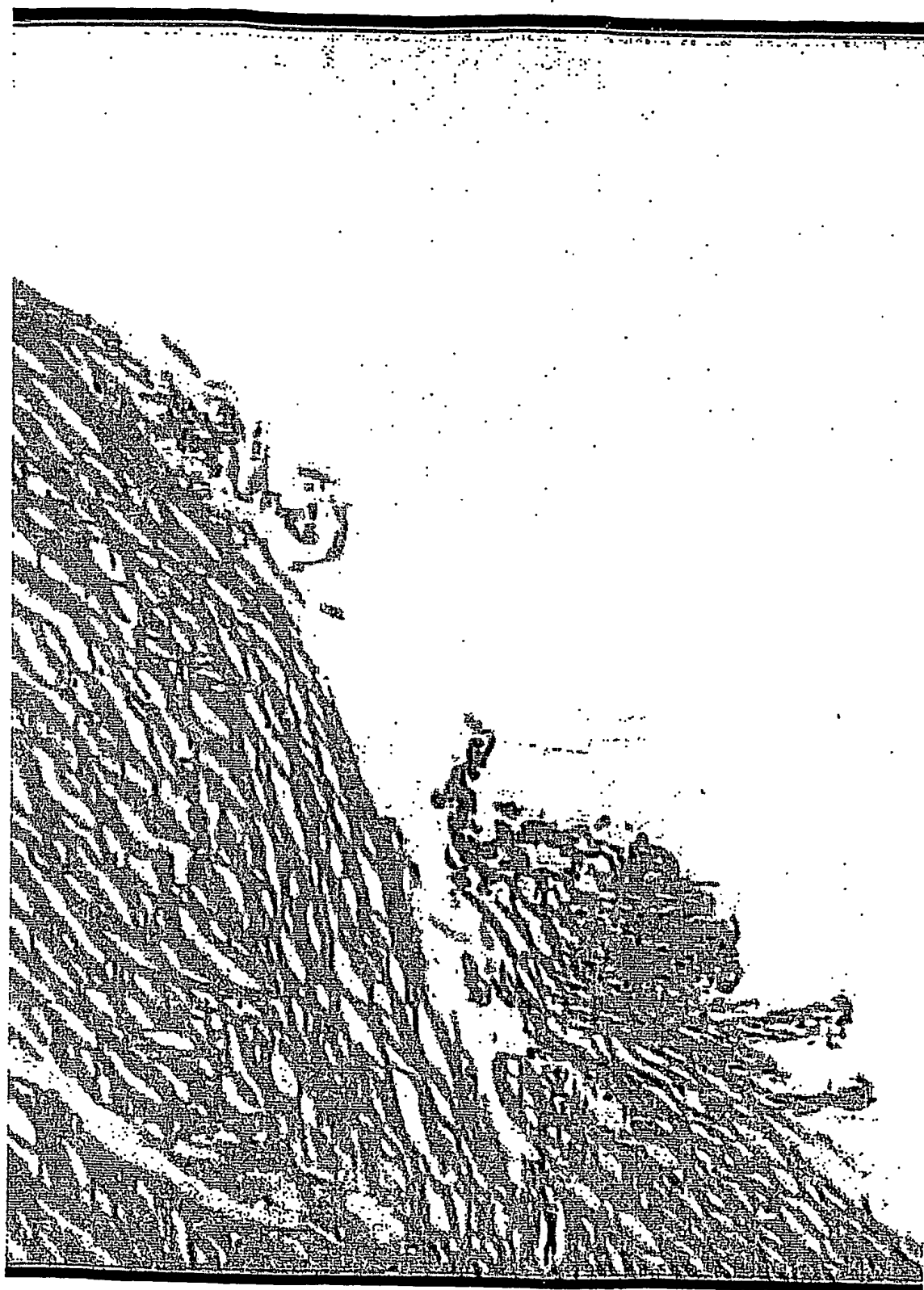
Tearing



Goniotome

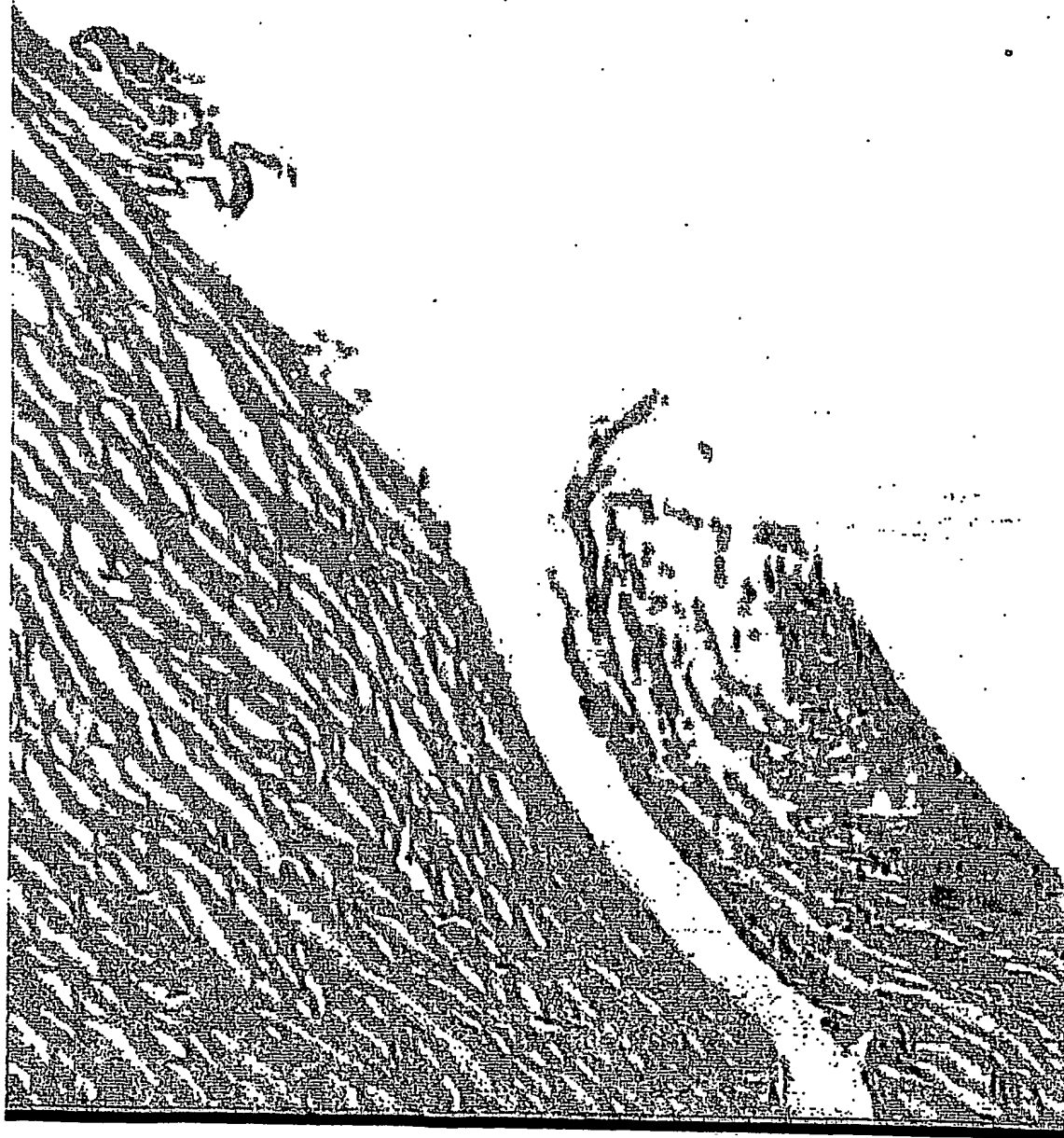


Goniectome 0.3 Watts



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Goniectome 0.7 Watts



60477258 .061002

Conclusion

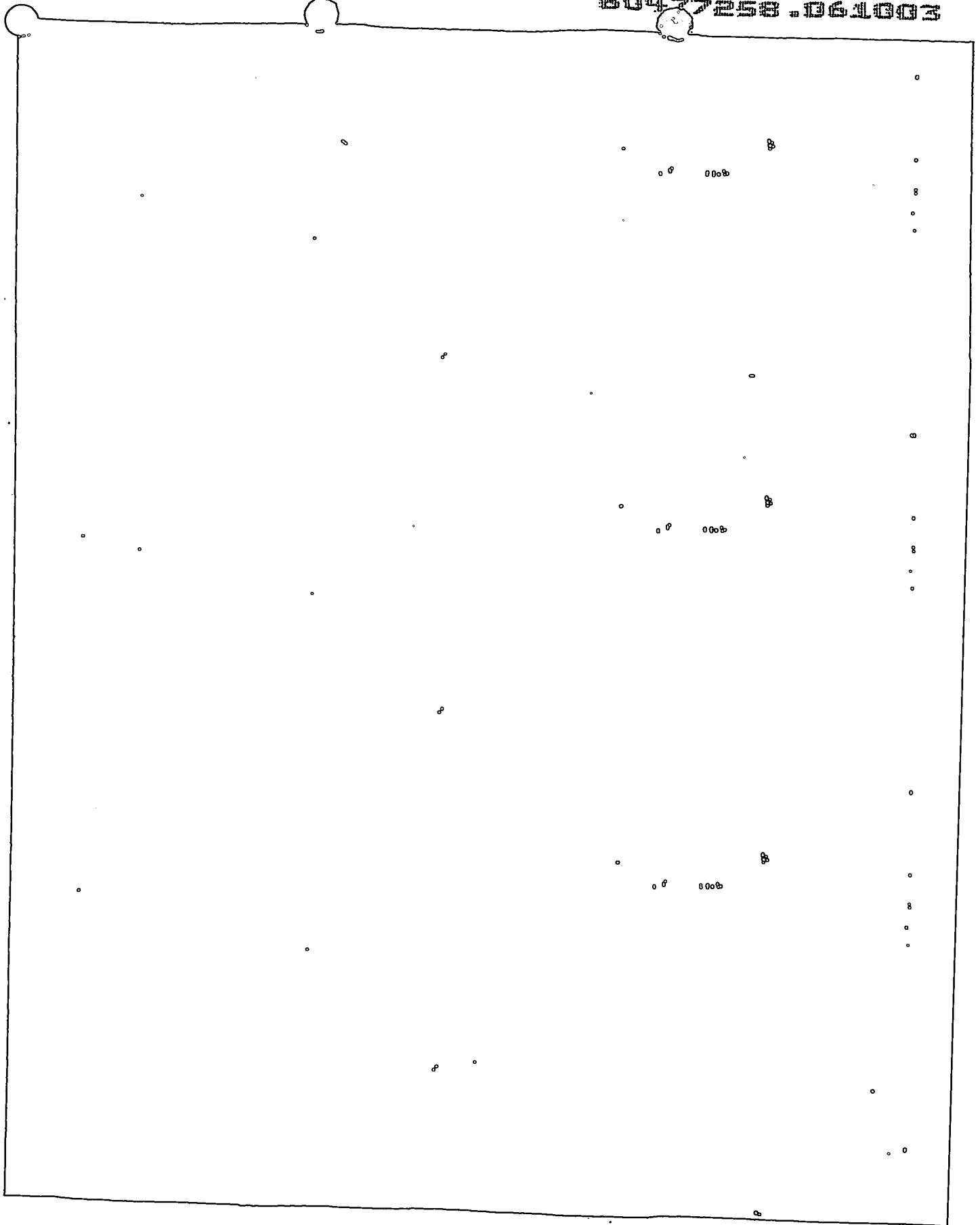
- Minimally invasive glaucoma surgery
- Integrated goniotome system
- Electrocautery for ablation
- Ablation of pigmented trabecular meshwork
- Opening Schlemm's canal into the AC
- Histology demonstrates reasonably acceptable thermal collateral damage
- Endothelial cells demonstrate minimal damage
- Effect on collector channels ?
- The proof of the pudding is in the eating thereof

GONIECTOMY PROJECT

NEOMEDIX
Corporation

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60477258.061003



OVERVIEW - GLAUCOMA

Disease and Intervention

Project Review

Regulatory Plan

Definition of Glaucoma:

Loss of Vision caused by the Destruction of the Optic Nerve

Types of Glaucoma

1. Primary Open Angle Glaucoma
2. Secondary Glaucoma
3. Normal Tension Glaucoma
4. Pigmentary Glaucoma
5. Closed Angle Glaucoma

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OVERVIEW - GLAUCOMA

Disease and Intervention

Project Review

Regulatory Plan

Primary Open-angle Glaucoma

Major Risk Factors:

- High Intraocular Pressure (IOP)
- Age
- Race
- Diabetes
- Systemic Hypertension

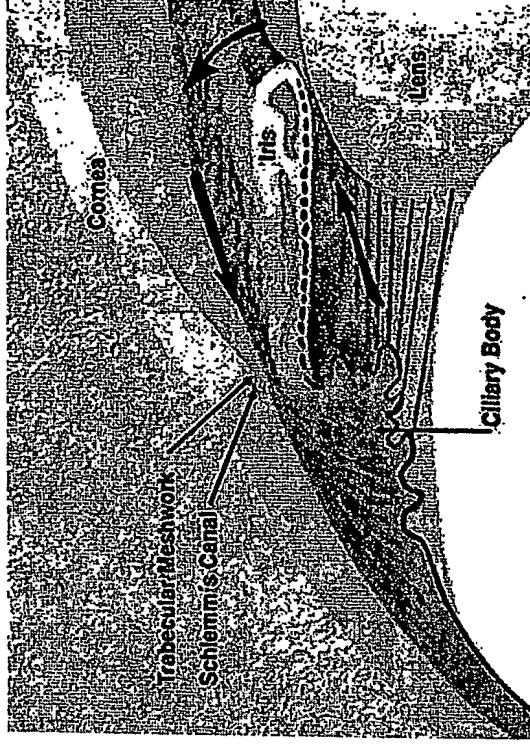


Figure Provided by the Intl. Glaucoma Association

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Corporation

GLAUCOMA TREATMENT

Disease and Invention

Project Review

Regulatory Plan

Current Technologies and their

Drawbacks

Medication

Filtering Surgery

Goniotomy Surgery

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Corporation

60477258 . 06100 W

GLAUCOMA TREATMENT

Disease and Invention

Project Review

Regulatory Plan

Intraocular Surgery Goniotomy

Using surgical knives to cut an opening or openings into the Trabecular meshwork.

Surgery is to increase the drainage of intraocular fluid from the eye.

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Corporation

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GLAUCOMA TREATMENT

Disease and Invention

Project Review

Regulatory Plan

Intraocular Surgery Goniotomy

- In children there is a 90% success rate due to TM elasticity.
- In adults, the drainage holes often close due to TM's pliability and patient's healing process.

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Corporation

047250 - 06100 W

GONIECTOMY TECHNOLOGY

Development

Disease and Invention

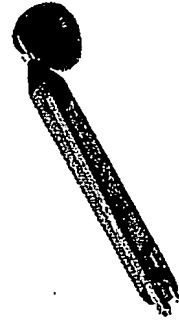
Product Review

Regulatory Plan

NEW Technology:

Goniotomy System

Completed by opening and removing a strip of the Trabecular meshwork in a highly atraumatic fashion.



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Corporation

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GONIECTOMY TECHNOLOGY

Development

Disease and Invention

Project Review

Regulatory Plan

Theory Behind the Approach

If the TM is the principle outflow-limiting component, then a large opening with a defined edge that maintains the patient's Schlemm's canal and collector channels will result in significant, permanent IOP reduction (analogous to the goniotomy in children).

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GONIECTOMY TECHNOLOGY

Development

Disease and Invention

Project Review

Regulatory Plan

Goniectomy: Reduce Eye Pressure

- Sections of the clogged meshwork are removed by mechanical or electro-surgical means.
- These open sections allow fluid flow into the Schlemm's canal and out of the eye through the normal collector channels. This decreases the I.O.P. to low, normal levels.
- This pressure reduction prevents or reduces damage to the optic nerve.

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5047250 . 061002

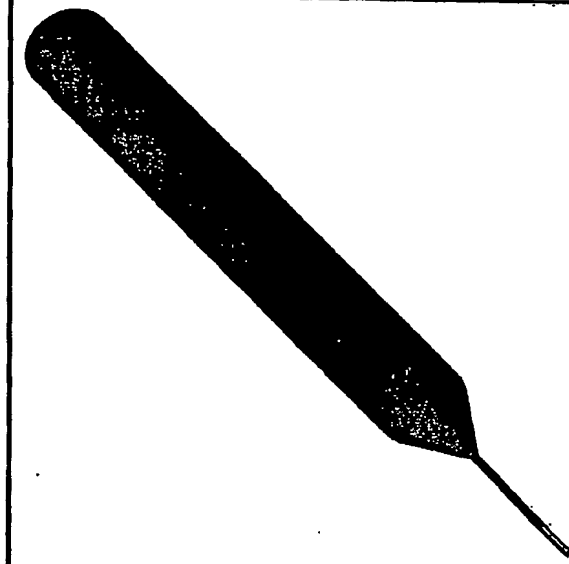
GONIECTOMY DEVICE Development History

Disease and Invention

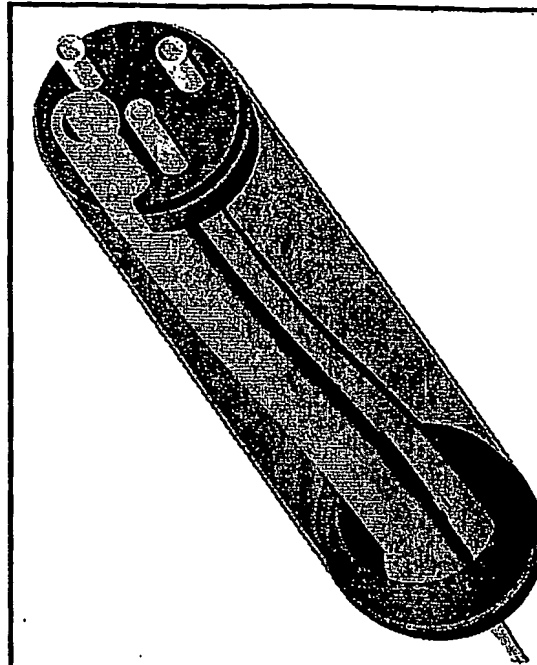
Project Review

Regulatory Plan

Electrosurgical Goniectomy *Concept: Integration into Handpiece*



glaucoma history feb 10 02 e
surface assem x2 full view.jpg



glaucoma history may 10 02 e
assem may 02 x2.jpg

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GONIECTOMY DEVICE

Development History

Disease and Invention

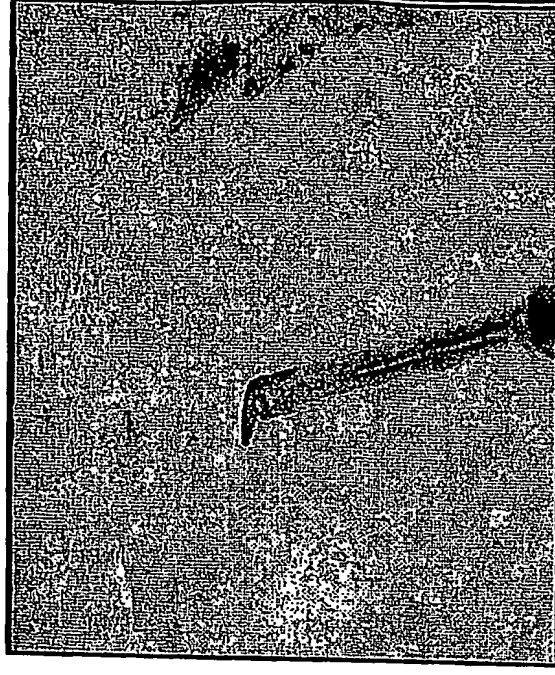
Project Review

Regulatory Plan

Clinical Goniectomy

Conclusions:

1. The footplate was able to guide the blade along the meshwork successfully.
2. Coated footplate insulated the SC tissue well.
3. Design allows for easy and safe removal of TM in an atraumatic manners.



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GONIECTOMY DEVICE

Development History

Disease and Invention

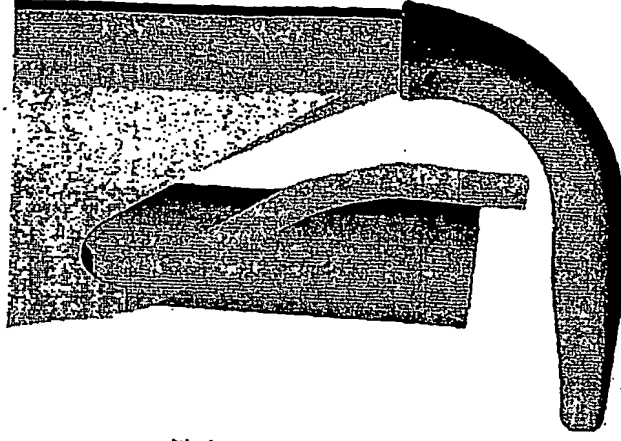
Project Review

Regulatory Plan

Electrosurgical Goniectomy

Alternative Design

1. This design supports irrigation and aspiration.
2. Electrosurgical cutting means are independent of Footplate.
3. Discharge center electrode to Return electrode.
4. Insulated guiding Footplate.



glaucoma history jul 31 02 assem electrodes x1.jpg 0.02"

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CORPORATION

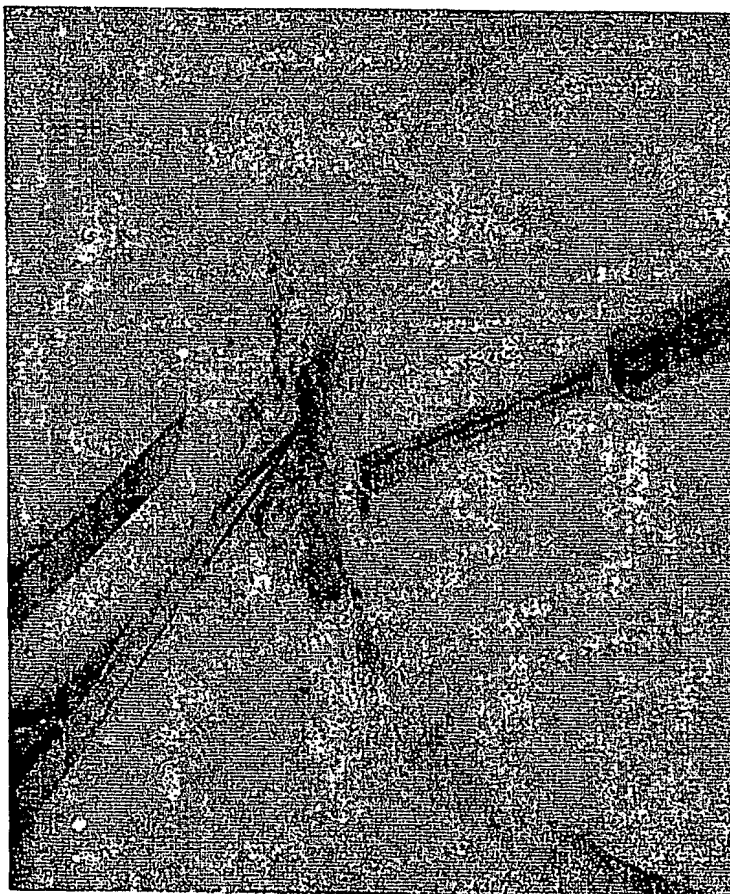
GONIECTOMY TECHNOLOGY In the Clinical Environment

Disease and Invention

Project Review

Regulatory Plan

Goniectomy Device - Clinical Version

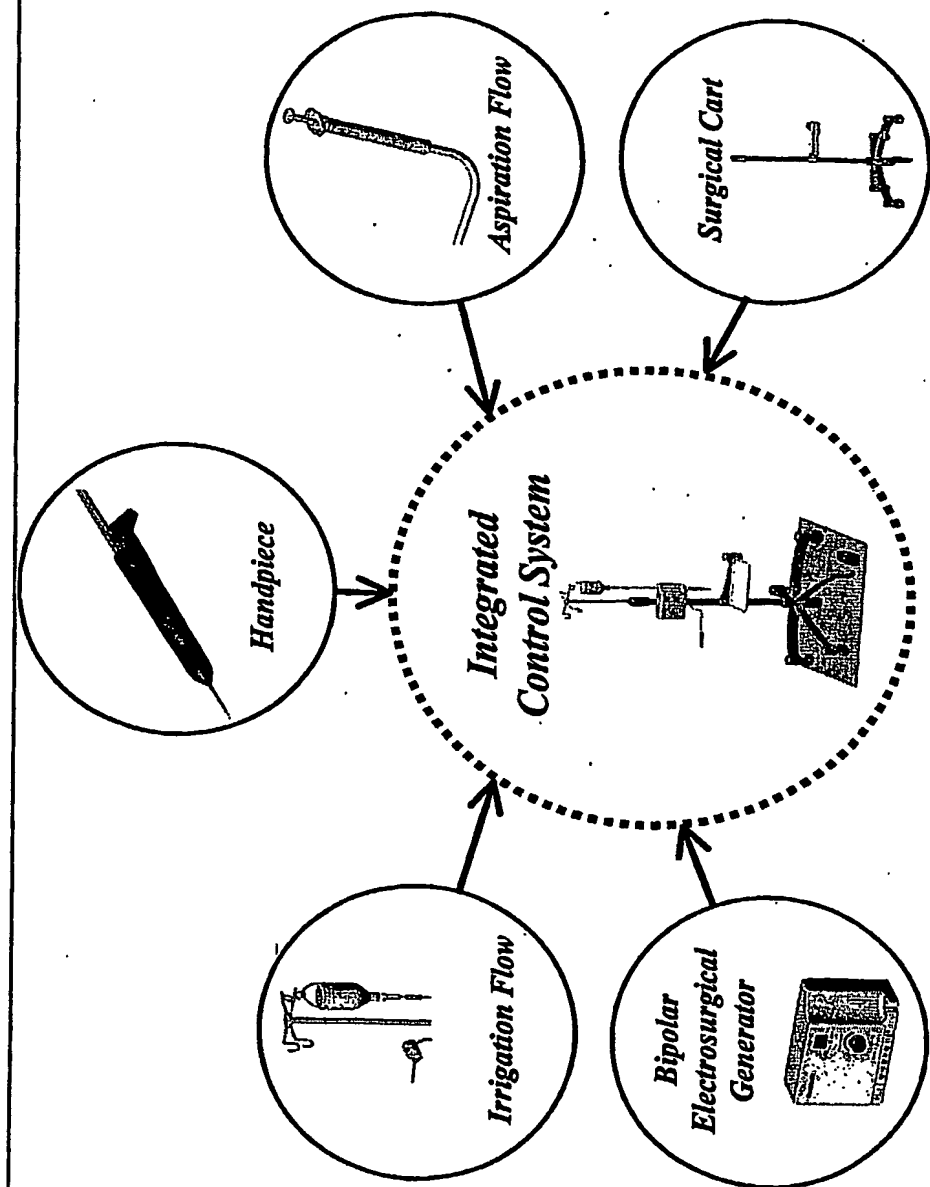


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GONIECTOMY TECHNOLOGY

Integrated Control System



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GONIECTOMY TECHNOLOGY

Integrated Control System

Disease and Invention

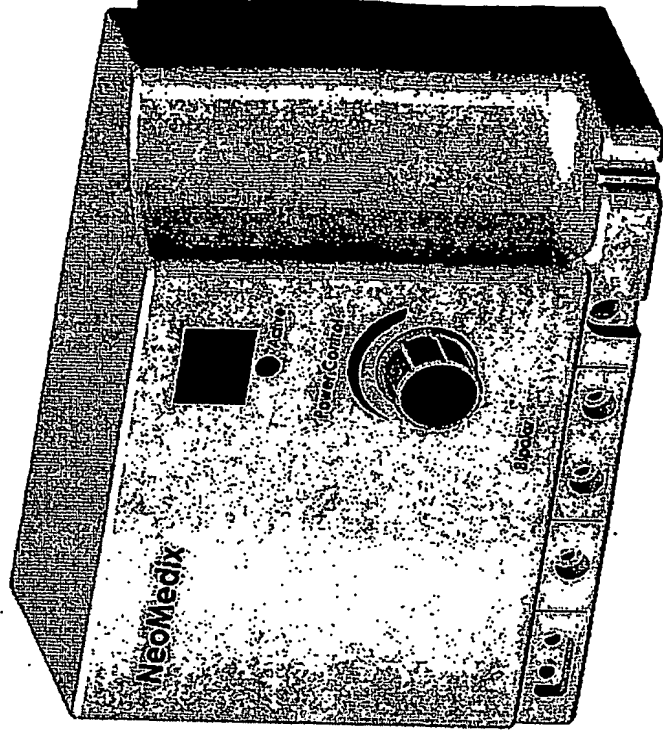
Project Review

Regulatory Plan

Console Integration Elements:

Electrosurgical Sub-System

- Full FDA and European regulatory approval
- Bipolar and monopolar capable
- Adjustable bipolar power levels from 0.1 to 30W
- Remote foot pedal control
- OEM private label



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GONIECTOMY TECHNOLOGY

Integrated Control System

Disease and Invention

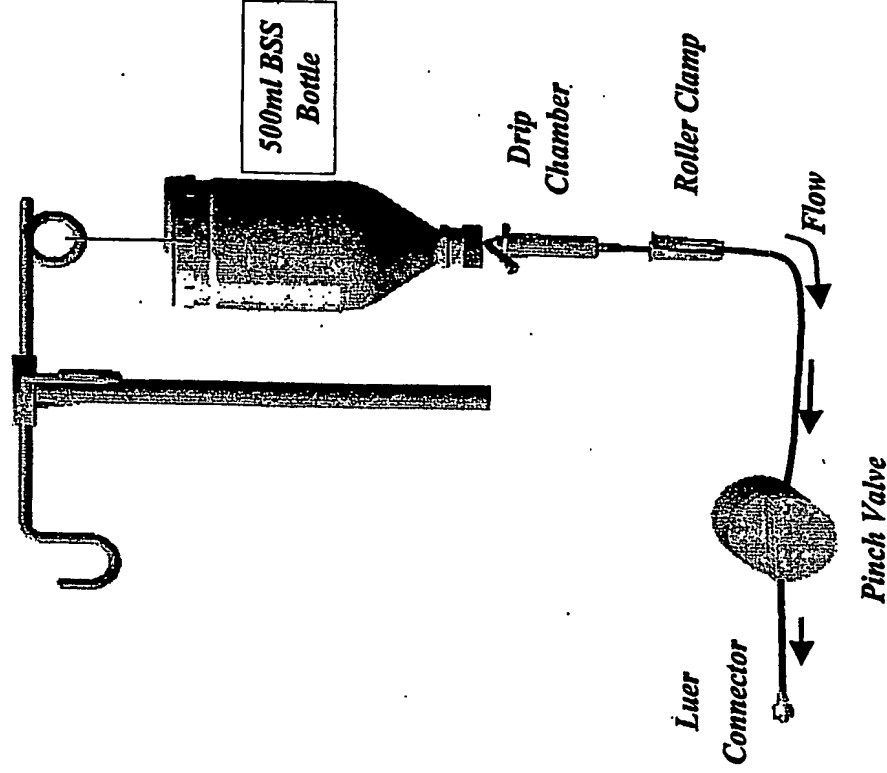
Project Review

Regulatory Plan

Console Integration:

Irrigation Sub-System

- Gravity fed irrigation of standard 500ml BSS bottle
- Adjustable bottle pole height
- Normally open pinch valve for safety
- Disconnect fitting allows for handpiece exchange



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GONIECTOMY TECHNOLOGY

Integrated Control System

Disease and Invention

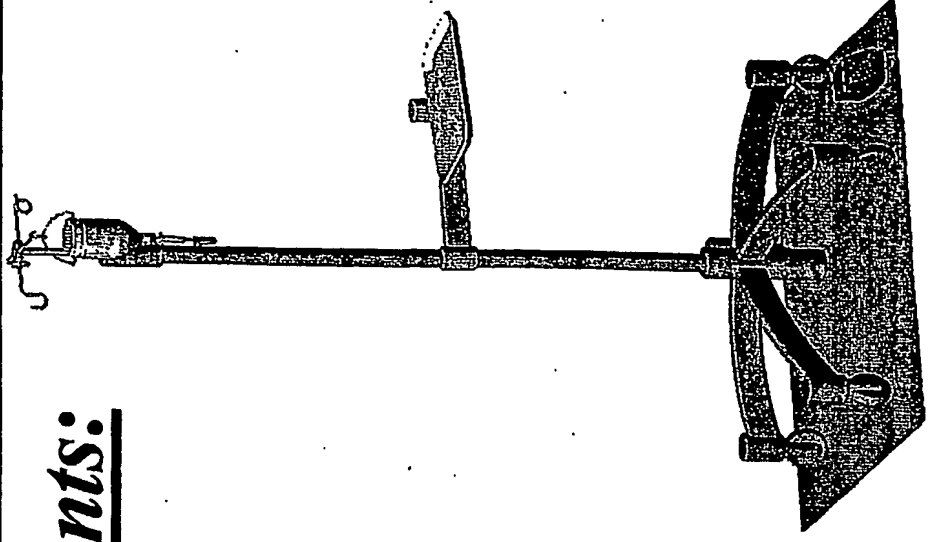
Product Review

Regulatory Plan

Console Integration Elements:

Surgical Cart

- Rolling surgical cart stands
- Adjustable irrigation bottle height mechanism
- Surgical tray for temporary holding of handpiece and tray packs



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GONIECTOMY TECHNOLOGY

Integrated Control System

Disease and Invention

Project Review

Regulatory Plan

Applicable Regulatory Standards

- FDA 510(k) (Class II)
- UL/cUL 2601
- IEC601
- IEC60601 [Medical Device Directive]
- IEC60417-1 [Graphical Symbols Standard]

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GONIECTOMY TECHNOLOGY

Integrated Control System

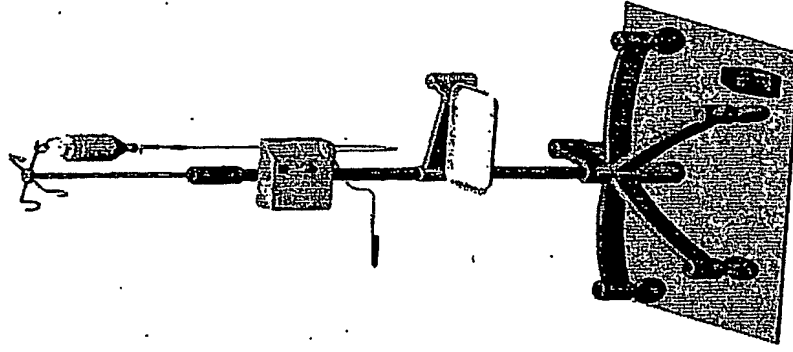
Disease and Invention

Project Review

Regulatory Plan

Integrated Console :

- Fluid Flow Control
- Irrigation
- Aspiration (Syringe)
- Electrosurgical Power



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GONIECTOMY TECHNOLOGY

Integrated Control System

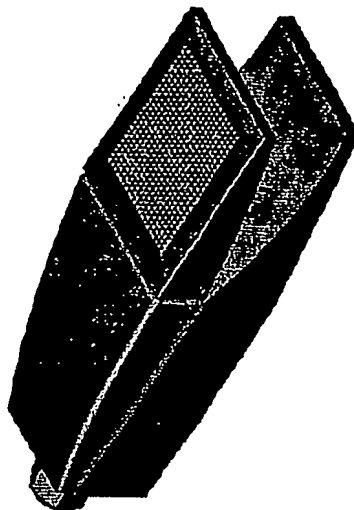
Disease and Invention

Project Review

Regulatory Plan

Footpedal control system

<i>Footpedal</i>	<i>Function</i>
Region 0	OFF
Region 1	Electrosurgical ON



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GONIECTOMY TECHNOLOGY

Disease and Invention

Project Review

Regulatory Plan

NeoMedix

Quality Plan

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GONIECTOMY TECHNOLOGY

Quality Plan

Disease and Invention

Project Review

Regulatory Plan

NeoMedix Development Project

Production Development Phases:

1. Prototype
2. Clinical
3. Pre-Production
4. Production

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Corporation

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GONIECTOMY TECHNOLOGY

Quality Plan

Disease and Invention

Project Review

Regulatory Plan

NeoMedix Development Project

Prototype Phase:

- | | |
|---------------------------------------|---|
| 1. User Requirement Specification | 8. Clinical Investigation (If applicable) |
| 2. Product Specification (Functional) | 9. Draft of Labeling |
| 3. Initial FMEA (EN 1441) | 10. Documentation |
| 4. In Vitro Testing | 11. Design review |
| 5. In Vivo Testing | 12. Process Requirement Defined |
| 6. Biocompatibility Method | 13. Special and Key Processes Identified |
| 7. Sterilization Method | 14. Receiving Inspection |

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GONIECTOMY TECHNOLOGY

Quality Plan

Disease and Invention

Project Review

Regulatory Plan

NeoMedix Development Project

Clinical Phase:

- | | |
|------------------------------------|-----------------------------------|
| 1. Validation Test Report | 8. Labeling Completed |
| 2. Completed FMEA | 9. Environmental Controls |
| 3. Equipment Validation | 10. Vendor Qualification |
| 4. Process Control in Place | 11. Manufacturing Instruction |
| 5. Biocompatibility Completed | 12. Process Instruction |
| 6. Sterilization Validation Report | 13. Drawings Release |
| 7. Design Review | 14. Bill of Materials Release |
| | 15. In-process, Final Instruction |
| | 16. Device History Record |

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GONIECTOMY TECHNOLOGY

Quality Plan

Disease and Invention

Project Review

Regulatory Plan

NeoMedix Development Project

Pre-Production:

1. FDA Clearance
2. Foreign Approvals (CE)
3. Design Review
4. Document Release
5. Device Master Record
6. Corrective Action System

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Corporation

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GONIECTOMY TECHNOLOGY

Quality Plan

Disease and Invention

Project Review

Regulatory Plan

NeoMedix Development Project

Production:

1. Failure Analysis Performed
2. Corrective Action System
3. Internal Audits Performed
4. Design Review
5. Documents Release

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GONNECTOMY PROJECT

NEOMEDIX
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OVERVIEW - GLAUCOMA

Disease and Invention

Project Review

Regulatory Plan

Definition of Glaucoma:

Loss of Vision caused by the Destruction of the Optic Nerve

Types of Glaucoma

1. Primary Open Angle Glaucoma
2. Secondary Glaucoma
3. Normal Tension Glaucoma
4. Pigmentary Glaucoma
5. Closed Angle Glaucoma

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OVERVIEW - GLAUCOMA

Disease and Invention

Project Review

Regulatory Plan

Primary Open-angle Glaucoma

Major Risk Factors:

- High Intraocular Pressure (IOP)
- Age
- Race
- Diabetes
- Systemic Hypertension

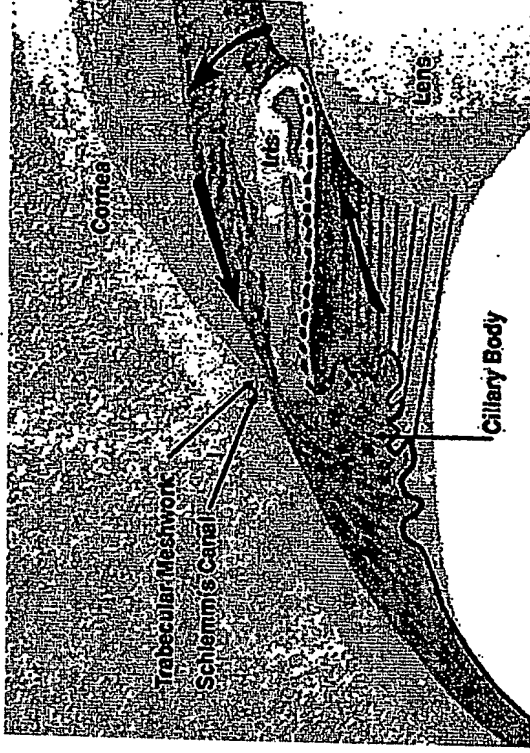


Figure Provided by the Intl. Glaucoma Association

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GLAUCOMA TREATMENT

Disease and Invention

Project Review

Regulatory Plan

Current Technologies and their Drawbacks

Medication
Filtering Surgery
Goniotomy Surgery

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Corporation

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GLAUCOMA TREATMENT

Disease and Invention

Project Review

Regulatory Plan

Intraocular Surgery

Goniotomy

Using surgical knives to cut an opening or openings into the Trabecular meshwork.

Surgery is to increase the drainage of intraocular fluid from the eye.

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Corporation

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GLAUCOMA TREATMENT

Disease and Intervention

Project Review

Regulatory Plan

Intraocular Surgery Goniotomy

- In children there is a 90% success rate due to TM elasticity.
- In adults, the drainage holes often close due to TM's pliability and patient's healing process.

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6047258 . 064004

GONIECTOMY TECHNOLOGY Development

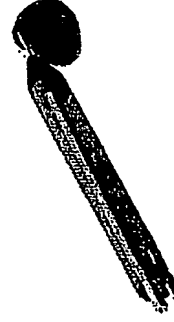
Disease and Invention

Project Review

Regulatory Plan

NEW Technology: Goniectomy System

Completed by opening and removing a strip of the
Trabecular meshwork in a highly atraumatic fashion.



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GONIECTOMY TECHNOLOGY

Development

Disease and Invention

Project Review

Regulatory Plan

Theory Behind the Approach

If the TM is the principle outflow-limiting component, then a large opening with a defined edge that maintains the patient's Schlemm's canal and collector channels will result in significant, permanent IOP reduction (analogous to the goniotomy in children).

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GONIECTOMY TECHNOLOGY

Development

Disease and Invention

Pre-Clinical Review

Regulatory Plan

Goniectomy: Reduce Eye Pressure

- Sections of the clogged meshwork are removed by mechanical or electro-surgical means.
- These open sections allow fluid flow into the Schlemm's canal and out of the eye through the normal collector channels. This decreases the I.O.P. to low, normal levels.
- This pressure reduction prevents or reduces damage to the optic nerve.

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GONIECTOMY DEVICE

Development History

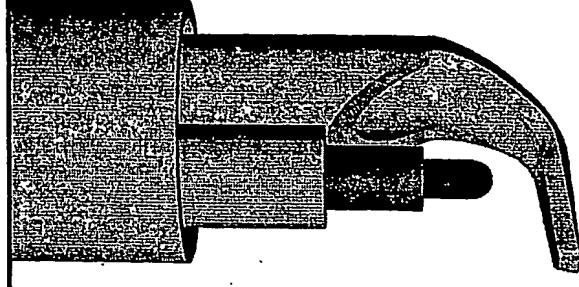
Disease and Invention

Project Review

Regulatory Plan

Powered Goniotomy

1. Three-tube design elements:
irrigation, aspiration, energy
delivery.
2. Footplate provides a guide
and protection of SC.
3. Choice of Multiple Forms of
Energy



glaucoma history nov 16 01 electro.jpg 0.05"

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5047250 . 04.1004

GONIECTOMY DEVICE Development History

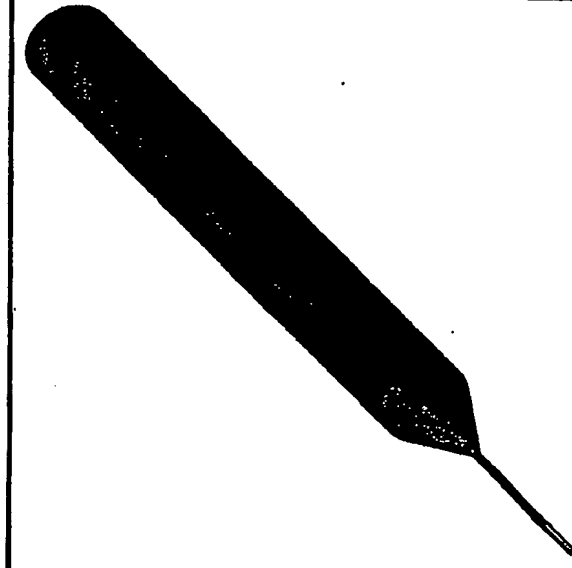
Disease and Invention

Project Review

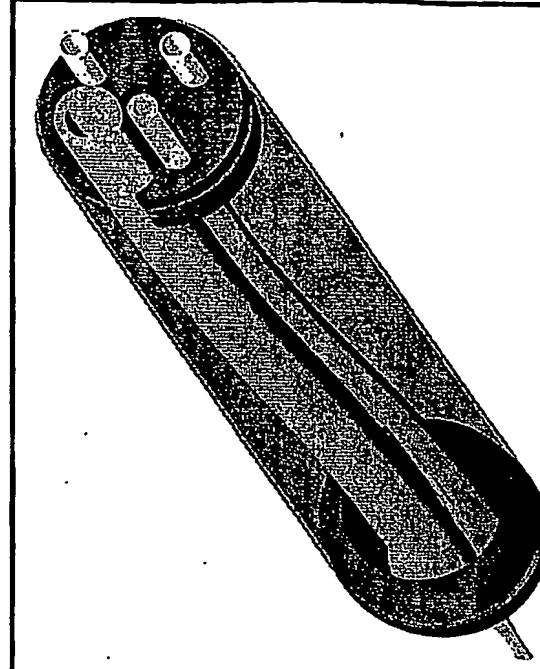
Regulatory Plan

Electrosurgical Goniectomy

Concept: Integration into Handpiece



glaucoma history feb 10 02 e
surface assem x2 full view.jpg



glaucoma history may 10 02 e
assem may 02 x2.jpg

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Corporation

6047258, 054004

GONIECTOMY DEVICE

Development History

Disease and Invention

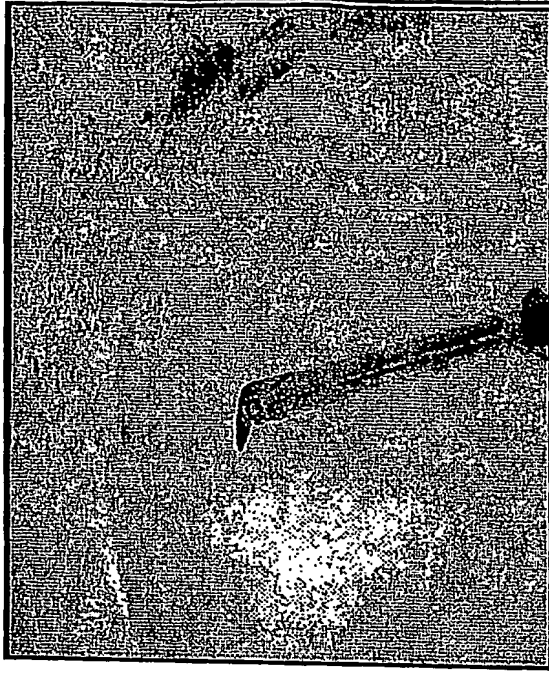
Project Review

Regulatory Plan

Clinical Goniectomy

Conclusions:

1. The footplate was able to guide the blade along the meshwork successfully.
2. Coated footplate insulated the SC tissue well.
3. Design allows for easy and safe removal of TM in an atraumatic manners.



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GONIECTOMY DEVICE Development History

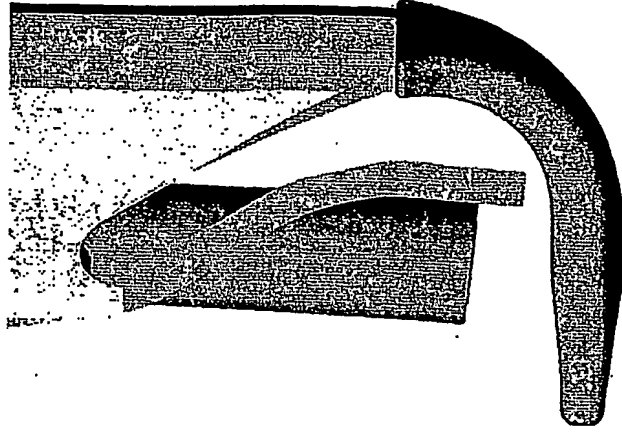
Disease and Invention

Project Review

Regulatory Plan

Electrosurgical Goniectomy *Alternative Design*

1. This design supports irrigation and aspiration.
2. Electrosurgical cutting means are independent of Footplate.
3. Discharge center electrode to Return electrode.
4. Insulated guiding Footplate.



glaucoma history jul 31 02 assem electrodes x1.jpg 0.02" |

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60477258 . 06490 W

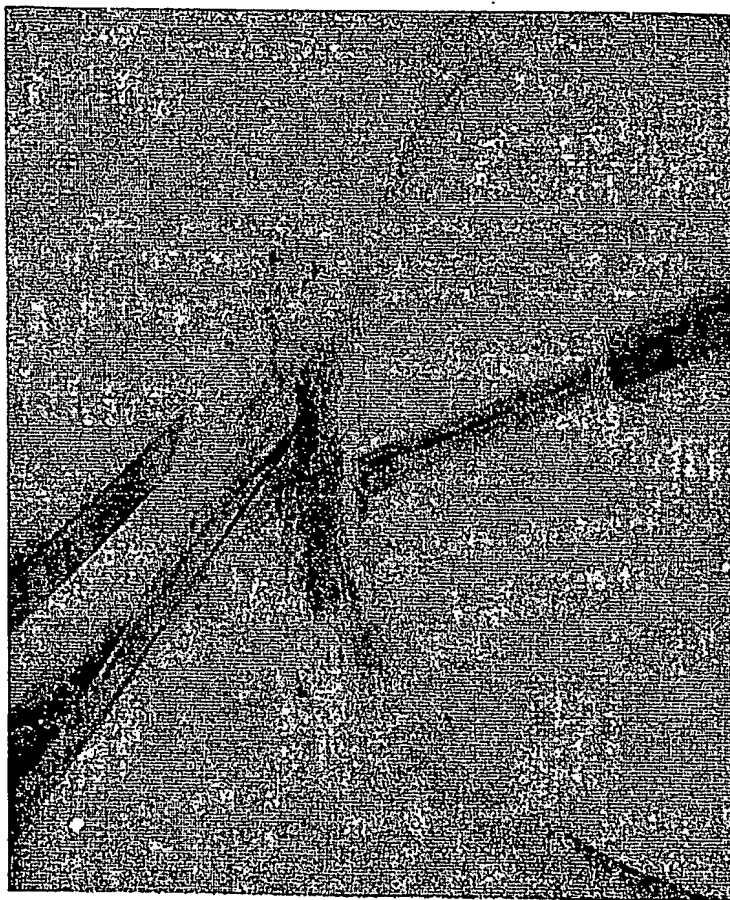
GONIECTOMY TECHNOLOGY In the Clinical Environment

Disease and Invention

Project Review

Regulatory Plan

Goniectomy Device - Clinical Version

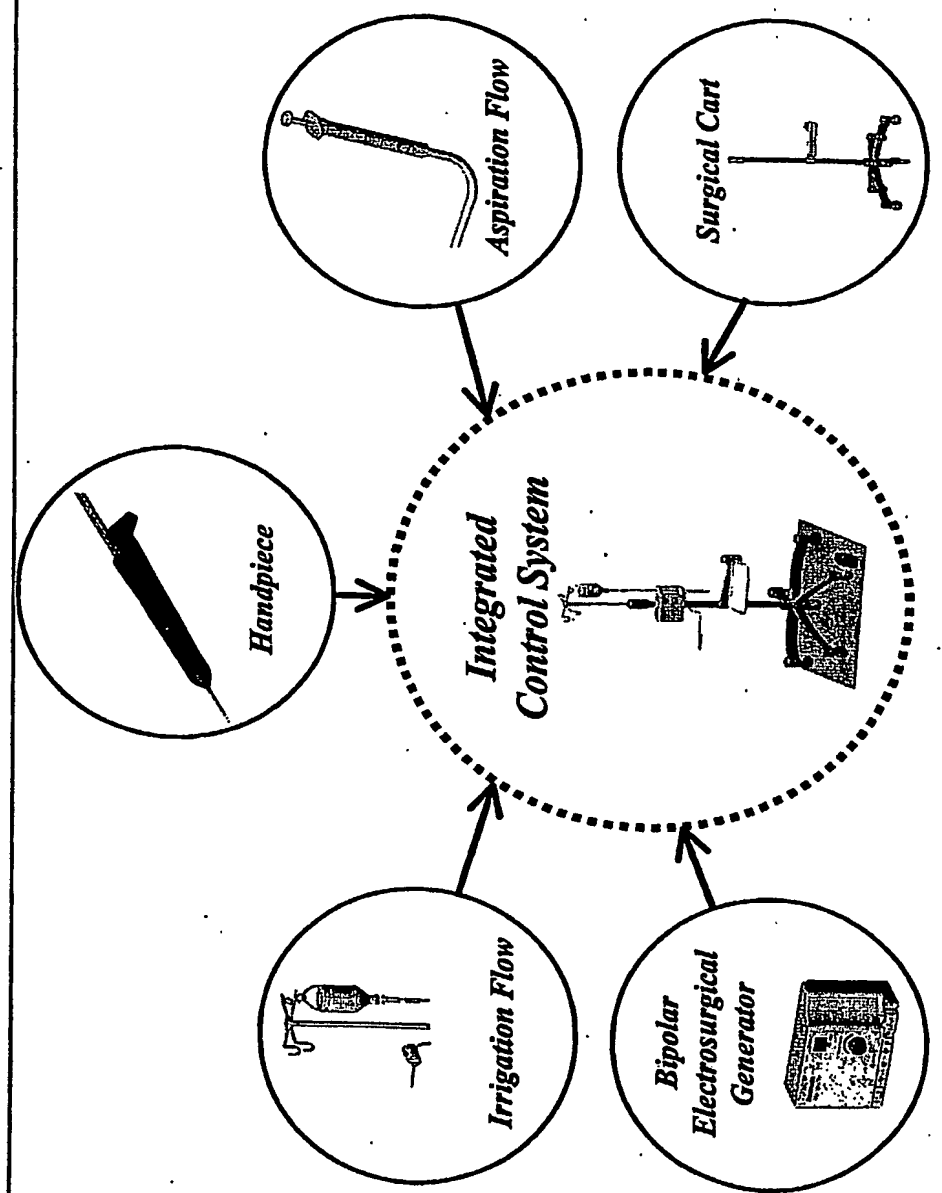


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GONIECTOMY TECHNOLOGY

Integrated Control System



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GONIECTOMY TECHNOLOGY

Integrated Control System

Disease and Invention

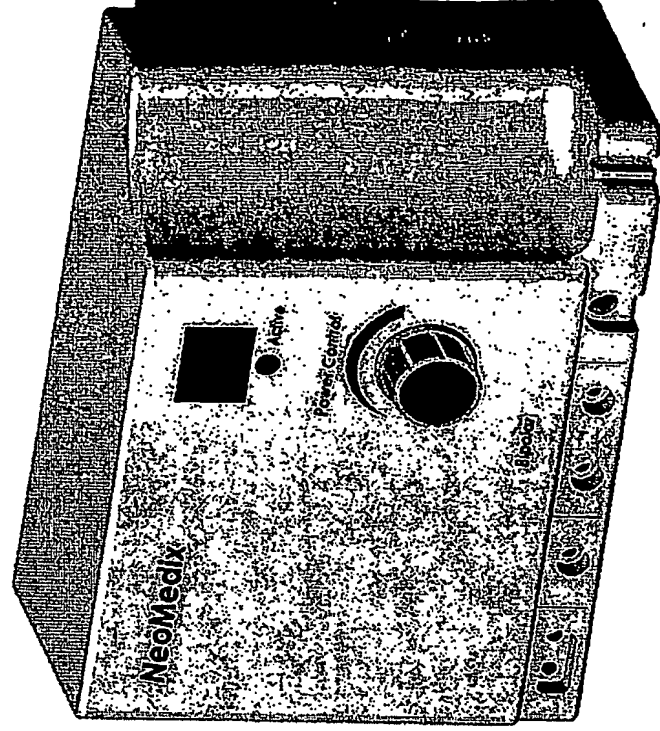
Project Review

Regulatory Plan

Console Integration Elements:

Electrosurgical Sub-System

- Full FDA and European regulatory approval
- Bipolar and monopolar capable
- Adjustable bipolar power levels from 0.1 to 30W
- Remote foot pedal control
- OEM private label



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GONIECTOMY TECHNOLOGY

Integrated Control System

Disease and Invention

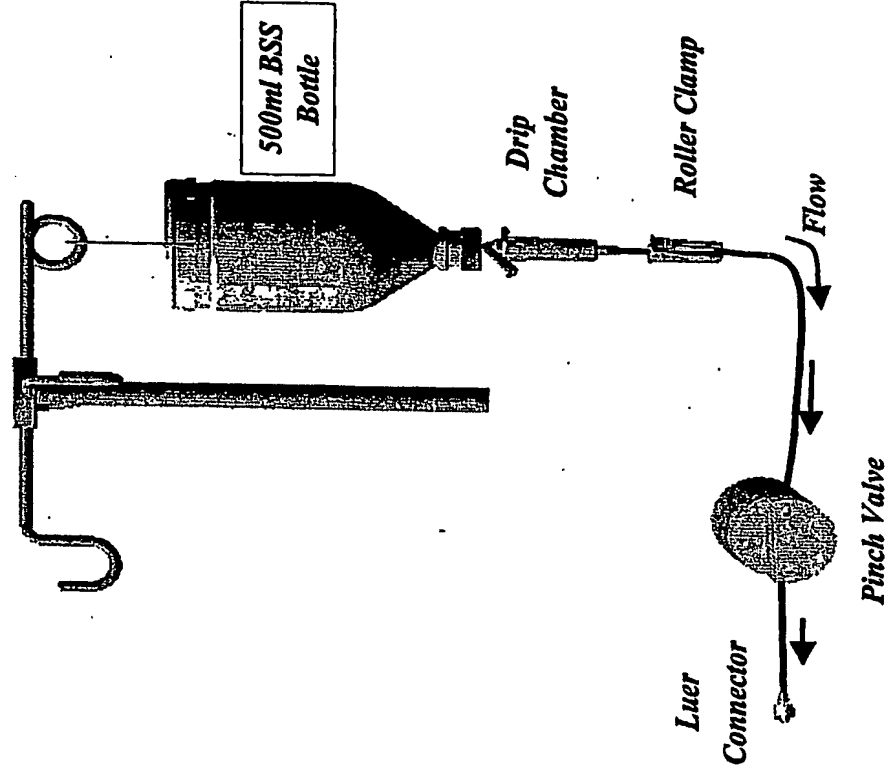
Project Review

Regulatory Plan

Console Integration:

Irrigation Sub-System

- Gravity fed irrigation of standard 500ml BSS bottle
- Adjustable bottle pole height
- Normally open pinch valve for safety
- Disconnect fitting allows for handpiece exchange



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Corporation

GONIECTOMY TECHNOLOGY

Integrated Control System

Disease and Invention

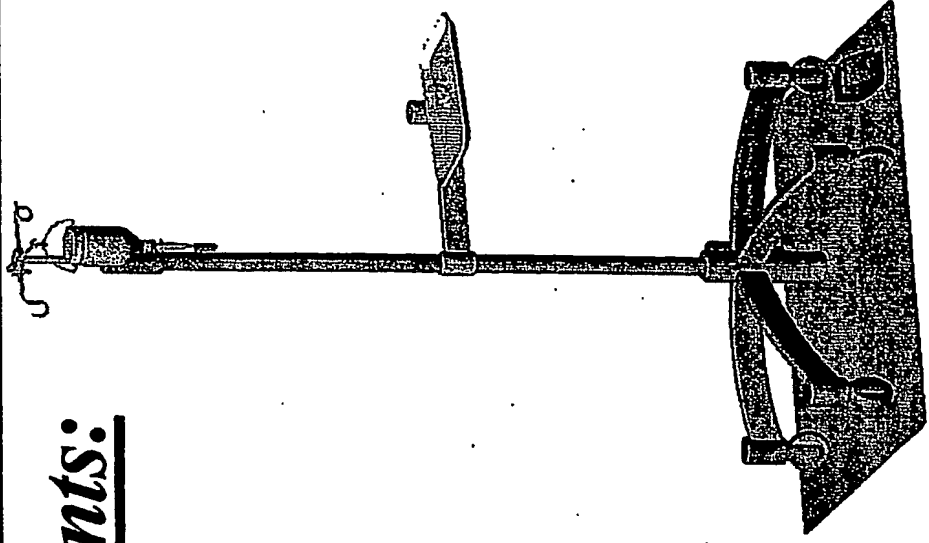
Product Review

Regulatory Plan

Console Integration Elements:

Surgical Cart

- Rolling surgical cart stands
- Adjustable irrigation bottle height mechanism
- Surgical tray for temporary holding of handpiece and tray packs



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Corporation

5047250, 06400W

GONIECTOMY TECHNOLOGY

Integrated Control System

Disease and Invention

Project Review

Regulatory Plan

Applicable Regulatory Standards

- FDA 510(k) (Class II)
- UL/cUL 2601
- IEC601
- IEC60601 [Medical Device Directive]
- IEC60417-1 [Graphical Symbols Standard]

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Corporation

60477250 . 064003

GONIECTOMY TECHNOLOGY

Integrated Control System

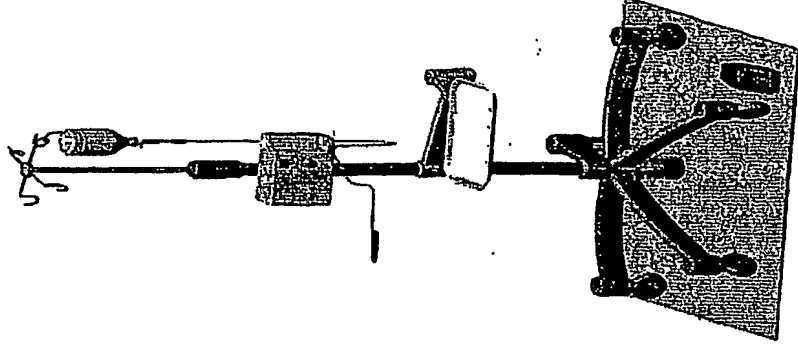
Disease and Invention

Product Review

Regulatory Plan

Integrated Console :

- Fluid Flow Control
- Irrigation
- Aspiration (Syringe)
- Electrosurgical Power



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GONNECTOMY TECHNOLOGY

Integrated Control System

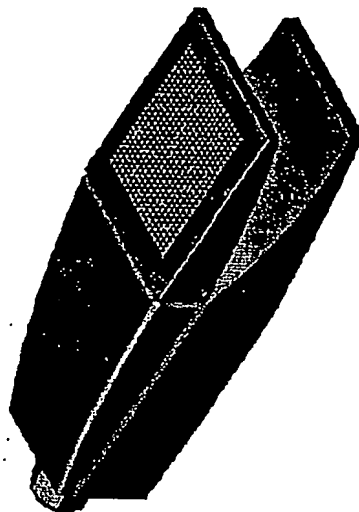
Disease and Invention

Project Review

Regulatory Plan

Footpedal control system

<i>Footpedal</i>	<i>Function</i>
Region 0	OFF
Region 1	Electrosurgical ON



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Corporation

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GONIECTOMY TECHNOLOGY

Disease and Invention

Project Review

Regulatory Plan

NeoMedix

Quality Plan

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Corporation

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GONIECTOMY TECHNOLOGY

Quality Plan

Disease and Invention

Project Review

Regulatory Plan

NeoMedix Development Project

Production Development Phases:

1. Prototype
2. Clinical
3. Pre-Production
4. Production

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GONIECTOMY TECHNOLOGY

Quality Plan

Disease and Invention

Project Review

Regulatory Plan

NeoMedix Development Project

Prototype Phase:

- | | |
|---------------------------------------|---|
| 1. User Requirement Specification | 8. Clinical Investigation (If applicable) |
| 2. Product Specification (Functional) | 9. Draft of Labeling |
| 3. Initial FMEA (EN 1441) | 10. Documentation |
| 4. In Vitro Testing | 11. Design review |
| 5. In Vivo Testing | 12. Process Requirement Defined |
| 6. Biocompatibility Method | 13. Special and Key Processes Identified |
| 7. Sterilization Method | 14. Receiving Inspection |

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GONIECTOMY TECHNOLOGY

Quality Plan

Disease and Invention

Project Review

Regulatory Plan

NeoMedix Development Project

Clinical Phase:

- | | |
|------------------------------------|-----------------------------------|
| 1. Validation Test Report | 8. Labeling Completed |
| 2. Completed FMEA | 9. Environmental Controls |
| 3. Equipment Validation | 10. Vendor Qualification |
| 4. Process Control in Place | 11. Manufacturing Instruction |
| 5. Biocompatibility Completed | 12. Process Instruction |
| 6. Sterilization Validation Report | 13. Drawings Release |
| 7. Design Review | 14. Bill of Materials Release |
| | 15. In-process, Final Instruction |
| | 16. Device History Record |

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GONIECTOMY TECHNOLOGY

Quality Plan

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NeoMedix Development Project

Pre-Production:

1. FDA Clearance
2. Foreign Approvals (CE)
3. Design Review
4. Document Release
5. Device Master Record
6. Corrective Action System

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GONIECTOMY TECHNOLOGY

Quality Plan

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NeoMedix Development Project

Production:

1. Failure Analysis Performed
2. Corrective Action System
3. Internal Audits Performed
4. Design Review
5. Documents Release

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GONIECTOMY PROJECT

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GONNECTOMY PROJECT

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GONIECTOMY PROJECT

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OVERVIEW - GLAUCOMA

Disease and Intervention

Project Review

Regulatory Plan

Definition of Glaucoma:

Loss of Vision caused by the Destruction of the Optic Nerve

Types of Glaucoma

1. Primary Open Angle Glaucoma
2. Secondary Glaucoma
3. Normal Tension Glaucoma
4. Pigmentary Glaucoma
5. Closed Angle Glaucoma

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604171250, 06/10/04

OVERVIEW - GLAUCOMA

Disease and Prevention

Project Review

Regulatory Plan

Primary Open-angle Glaucoma

Major Risk Factors:

- High Intraocular Pressure (IOP)
- Age
- Race
- Diabetes
- Systemic Hypertension

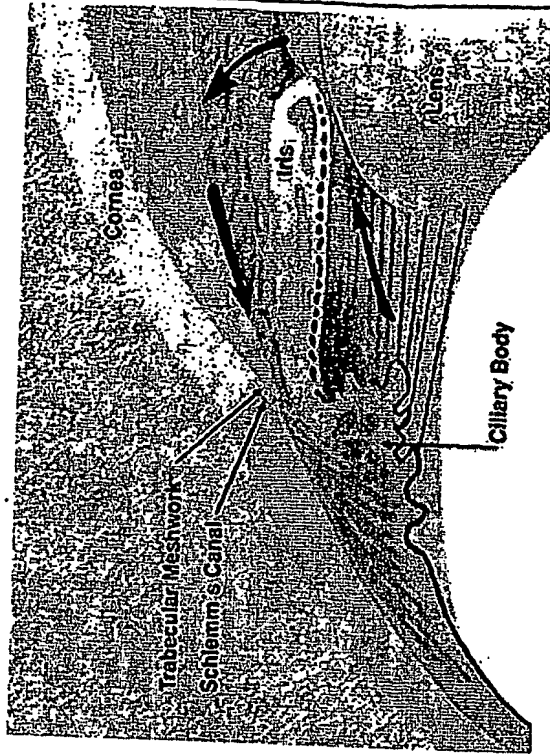


Figure Provided by the Intl. Glaucoma Association

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GLAUCOMA TREATMENT

Disease and Invention

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Current Technologies and their Drawbacks

Medication
Filtering Surgery
Goniotomy Surgery

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GLAUCOMA TREATMENT

Disease and Invention

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Medication

Eye drops are typically used to inhibit the high intraocular pressure.

1. Reduces production of intraocular fluid.
and / or
2. Increases drainage of intraocular fluid from the eye.

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GLAUCOMA TREATMENT

Disease and Invention

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Medication

Side Effects:

Often, the effects of taking the medication are not limited to the eye. Many cause headaches, fatigue, impaired night vision, stinging eyes, reduced cardiac output leading to low blood pressure, or shortness of breath.

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GLAUCOMA TREATMENT

Disease and Intervention

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Modern Medication Treatments

Glaucoma treatment often includes a combination of medications due to inadequate effects of a single drug. This in turn may cause a summation of unwanted side effects.

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GLAUCOMA TREATMENT

Disease and Invention

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Filtering Surgery

Drainage holes are created in the sclera to bypass the clogged filtering system in order to lower IOP.

Works as long as it increases the drainage of
intraocular fluid from the eye.

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GLAUCOMA TREATMENT

Disease and Invention

Project Review

Regulatory Plan

Filtering Surgery

Side Effects:

Over time the surgically created drainage holes tend to close and the pressure rises due to the patient's healing response. Additional risks include vision changes and risk of infection.

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GLAUCOMA TREATMENT

Disease and Invention

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Laser Trabeculoplasty

A highly concentrated beam of light (laser) is used to create multiple burns in the trabecular meshwork. These burns cause an increased outflow of fluid from the eye.

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GLAUCOMA TREATMENT

Disease and Invention

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Laser Trabeculoplasty

Side Effects:

IOP decrease is approximately equal to one medication.
Medication is still needed after surgery, in most cases.

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Disease and Intervention

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Regulatory Plan

Intraocular Surgery

Goniotomy

Surgical knives are used to cut an opening or openings into the Trabecular meshwork to allow fluid to drain from the eye.

Surgery works by increasing the drainage of intraocular fluid from the eye.

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GLAUCOMA TREATMENT

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Intraocular Surgery Goniotomy

In children there is a 90% success rate. In adults, the drainage holes often close due to the patient's healing response.

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GONIECTOMY PATENT

Disease and Invention

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Patent and Licensing of the Technology

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GONIECTOMY PATENT

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US Patent Published Aug. 15, 2002

Trabeculectomy instrument using cauterization, laser ablation, sonic, ultrasonic, or mechanically cutting to remove a portion of the meshwork. The instrument may be provided with I & A and a footplate plate to serve as a guide along the Schlemm's canal.



United States
Patent Application Publication
Barrett et al.

Pub. No.: US 2002/011608 A1
Pub. Date: Aug. 15, 2002

MINIMALLY INVASIVE GLAUCOMA
SURGICAL INSTRUMENT AND METHOD

Inventors: Gary Barrett, Marcus Bush, CA
(US), Gary Barrett, Irvine, CA (US)

Corresponding Address:
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620 NEWPORT CENTER DRIVE
SEVENTH FLOOR
NEWPORT BEACH, CA 92660 (US)

App. No.: 10/043,013
Filed: Jan. 18, 2002

Related U.S. Application Data

Provisional application No. 60/254,611, filed on Jan. 18, 2001.

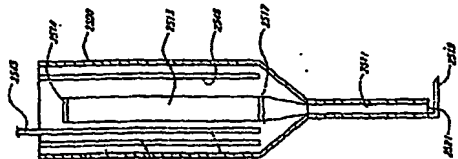
Publication Classification

(51) Int. Cl.⁷ A61B 1/24; A61B 1/26

(52) U.S. Cl. 606/404; 606/405; 606/406

ABSTRACT

Apparatus and method for the treatment of glaucoma are disclosed. The apparatus includes a handle, a footplate, and a cutting or ablation device. The footplate is positioned at a portion of the trabecular meshwork. The handle may also be provided with a footplate. The footplate may be provided with a footplate. The footplate may be provided with a footplate. The footplate may be provided with a footplate.



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GONIECTOMY PROJECT

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GONIECTOMY TECHNOLOGY Development

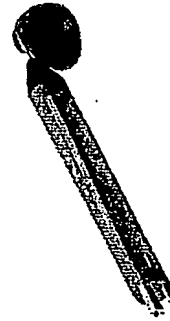
Disease and Invention

Project Review

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THE NEW SOLUTION: The Goniectomy System

Completed by opening and removing a strip of the
Trabecular meshwork in a highly atraumatic fashion.



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GONIECTOMY TECHNOLOGY

Development

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Theory Behind the Approach

If the Trabecular meshwork is the principle outflow limiting component, then a large opening with a defined edge that maintains the patient's Schlemm's canal and collector channels will result in significant, permanent IOP reduction (analogous to the goniotomy in children).

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GONIECTOMY TECHNOLOGY

Development

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Goniotomy: Reduce Eye Pressure

- Sections of the clogged meshwork are removed by mechanical or electrosurgical means.
- These open sections allow fluid flow into the Schlemm's canal and out of the eye through the normal collector channels. This decreases the I.O.P. to low, normal levels.
- This pressure reduction prevents or reduces damage to the optic nerve.

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GONIECTOMY TECHNOLOGY

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NeoMedix Development Project

1. History of Handpiece
2. Current Handpiece
3. Integrated Console System
4. Quality Plan

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GONIECTOMY DEVICE

Development History

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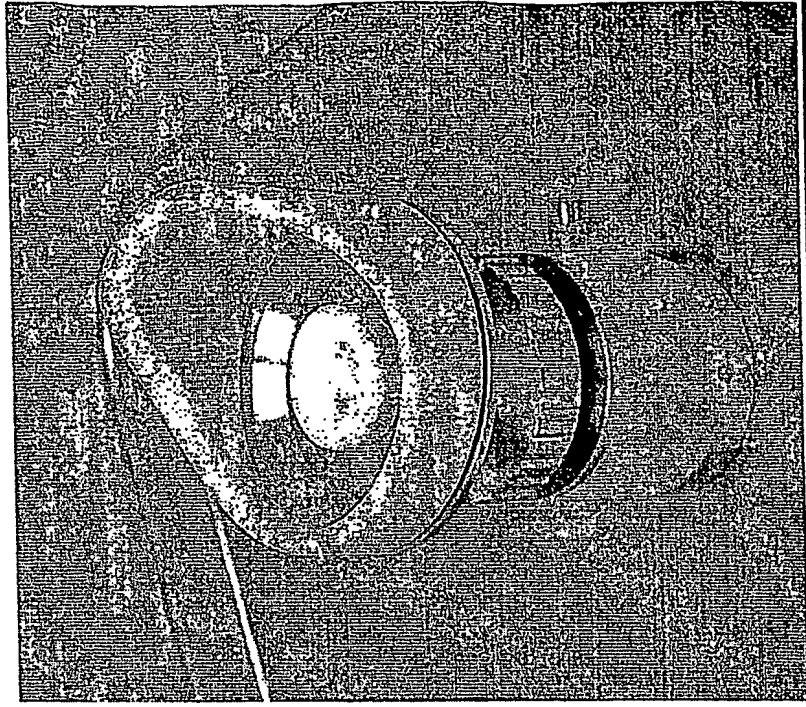
Project Review

Regulatory Plan

Goniectomy: Simulated Surgery

Cornea holder:

1. Conforming suction cup to retain cornea.
2. Tilt and rotate, lockable holder for convenient access.
3. Means to provide BSS environment for goniectomy.



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GONIECTOMY DEVICE

Development History

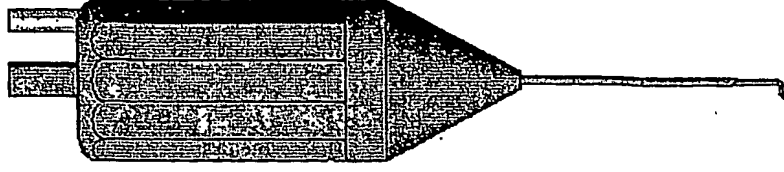
Disease and Invention

Project Review

Regulatory Plan

Bladed Goniectomy

1. Based on the bent surgical needle used originally.
2. Sharp pointed footplate to cut the meshwork.
3. Shape of the footplate allows the blade to be guided along the Schlemms canal.



Needle Cutter Handpiece

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GONIECTOMY DEVICE

Development History

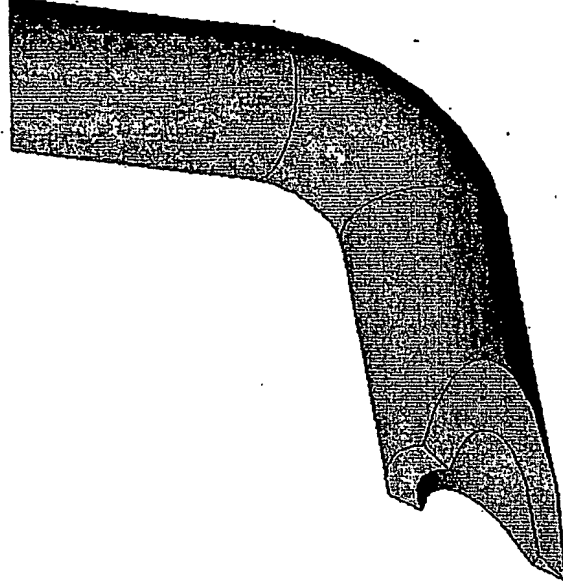
Disease and Invention

Project Review

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Mechanical Dual Cutting Goniectomy

1. Distal sides of tube facets form the cutting blades.
2. Means to separate a strip of meshwork.



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GONIECTOMY DEVICE

Development History

Disease and Invention

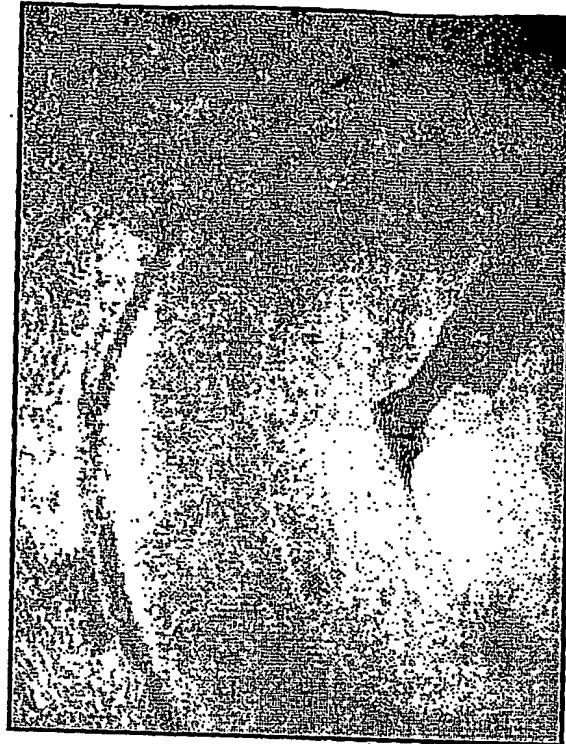
Project Review

Regulatory Plan

Bladed Goniectomy Design

Conclusions:

1. The footplate was able to guide the blade along the meshwork successfully.
2. Blade appeared to tear instead of cut the meshwork.



April early 2002

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GONIECTOMY DEVICE

Development History

Disease and Invention

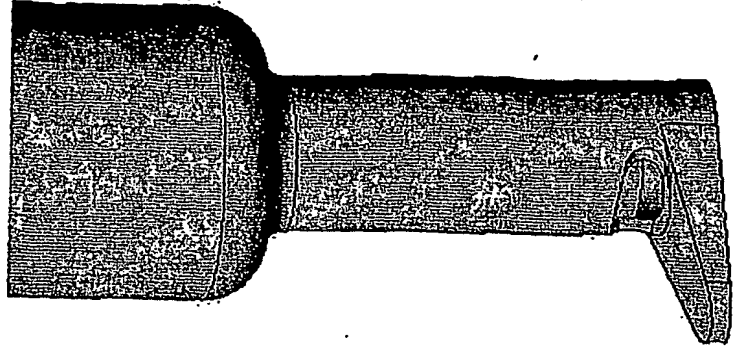
Project Review

Regulatory Plan

Mechanical Goniectomy

Guillotine Cutter

1. Reduced size working end.
2. Addition of a guiding foot to position tissue for nibbling cuts.
3. Trabecular meshwork slipped from the cutting elements on each stroke.



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GONIECTOMY DEVICE

Development History

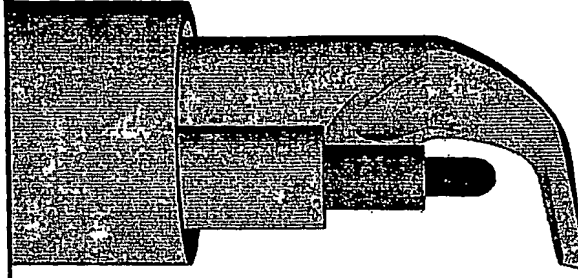
Disease and Invention

Project Review

Regulatory Plan

Powered Goniectomy

1. Three -tube design elements:
irrigation, aspiration, energy
delivery.
2. Footplate provides a guide.
3. Choice of Multiple Forms of
Energy



glaucoma history nov 16 01 electro.jpg 0.05"

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GONIECTOMY DEVICE

Development History

Disease and Invention

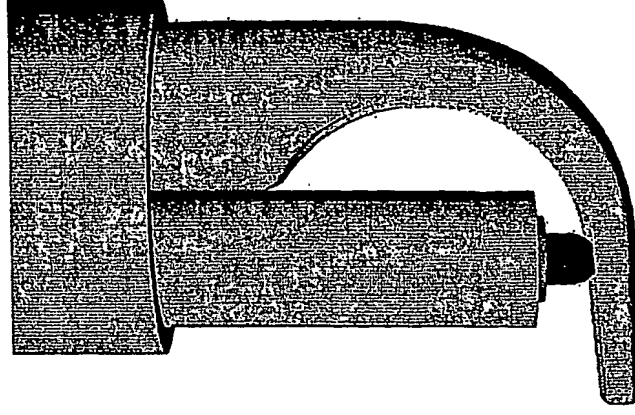
Product Review

Regulatory Plan

Electrosurgical Goniotomy

Insulating footplate Concept

1. Electrical and thermal non-conductive footplate to protect Schlemm's canal.
2. Radial discharge from center electrode to surrounding outer electrode.
3. Mechanical support of footplate by center electrode.



glaucoma history nov 19 01 insu footplate electro 6.jpg

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Regulatory Plan

Electrosurgical Goniectomy Plastic footplate Fabrication

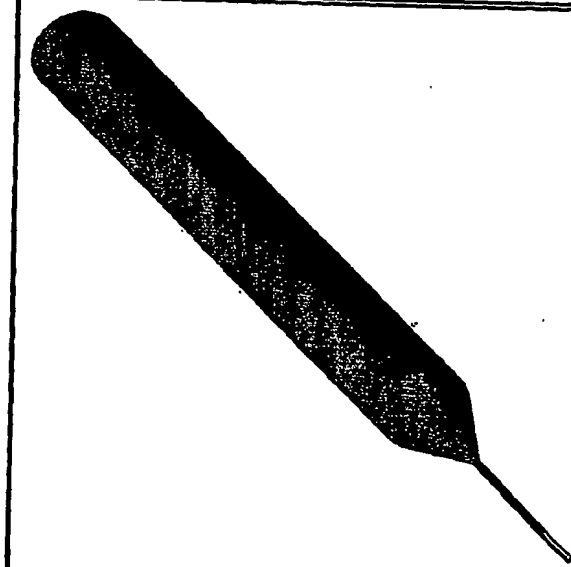
GONIECTOMY DEVICE Development History

Disease and Invention

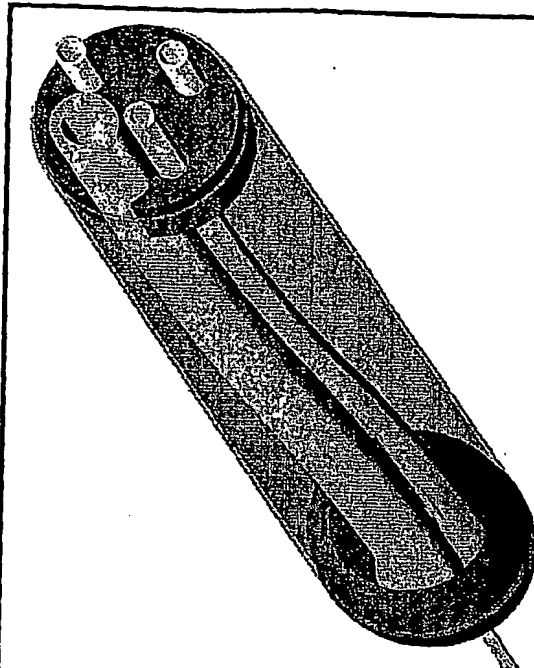
Project Review

Regulatory Plan

Electrosurgical Goniectomy *Concept: Integration into Handpiece*



glaucoma history feb 10 02 e
surface assem x2 full view.jpg



glaucoma history may 10 02 e
assem may 02 x2.jpg

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GONIECTOMY DEVICE

Development History

Disease and Invention

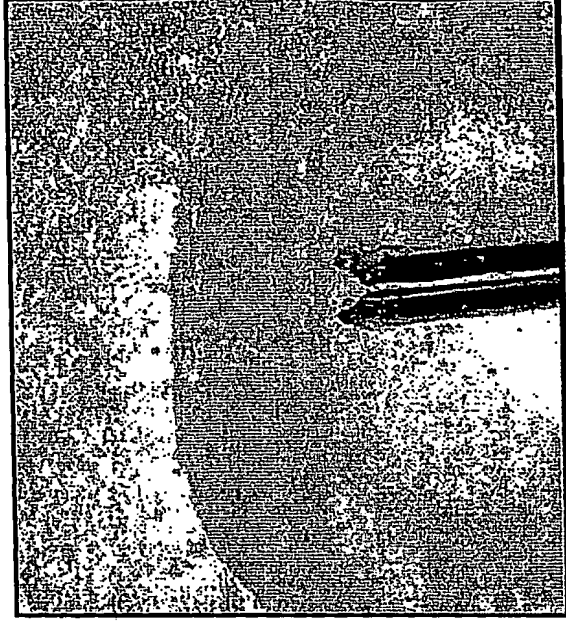
Project Review

Regulatory Plan

Electrosurgical Plastic footplate Goniectomy

Conclusion:

1. Plastic footplate was able to guide along Schlemm's Canal successfully.
2. Fabricating the plastic footplate and successfully bonding it to the tip of the handpiece was too time consuming.



Serial N: QO May 24 02 0.05" |-----|

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GONIECTOMY DEVICE Development History

Disease and Invention

Project Review

Regulatory Plan

Radial or Axial Discharge Electrosurgical Goniectomy with Non-insulated footplate



Serial N: 004 May 24 02



Serial N: 001 Apr 26 02

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GONIECTOMY DEVICE

Development History

Disease and Invention

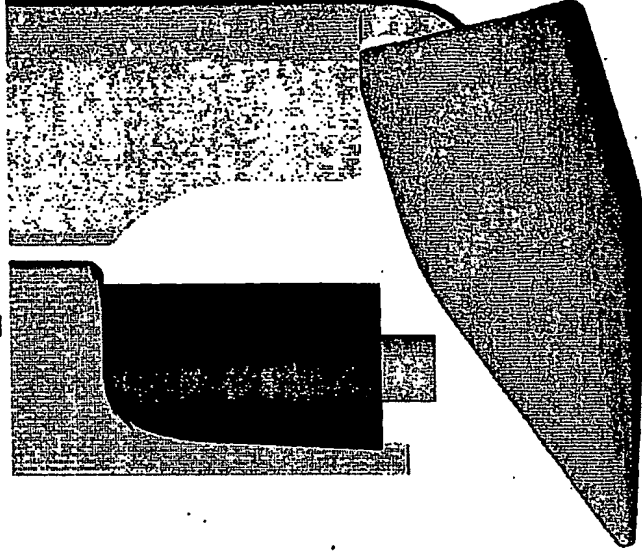
Project Review

Regulatory Plan

Electrosurgical Goniotomy

Insulated footplate Concept

- Micro-lathed and drilled plastic insulator.
- Glue plastic insulator over footplate
- Footplate is bent from an extension of the aspiration tube:



glaucoma history may 24 02 e asset may 02 x6.jpg 0.02" |-----|

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GONIECTOMY DEVICE

Development History

Disease and Invention

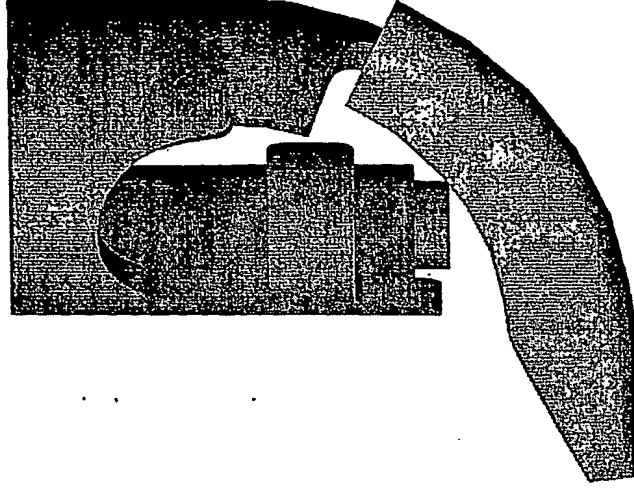
Project Review

Regulatory Plan

Electrosurgical Goniectomy

Insulated footplate Concept

1. Insulating tube covered footplate and formed tapered tip with glue.
2. Coaxial dual tube approach
3. Holding band formed from the horizontal extensions surrounding electrode insulation.



glaucoma history may 30 02 aspiration coax tube may 02x05.jpg 0.02" |

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GONIECTOMY DEVICE

Development History

Disease and Invention

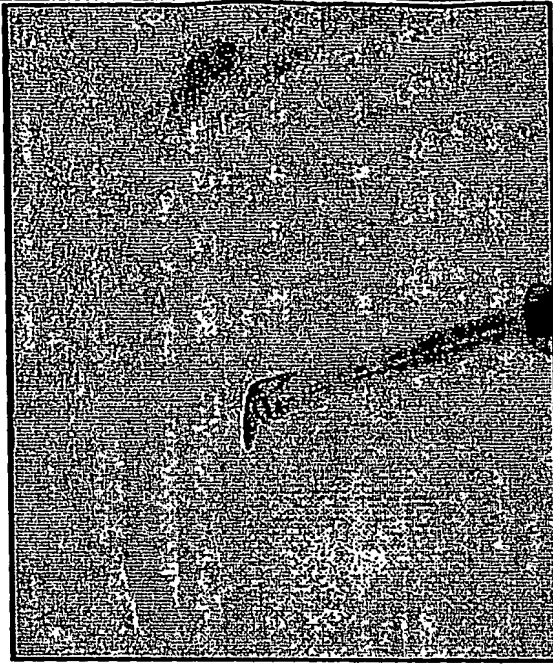
Project Review

Regulatory Plan

Clinical Goniectomy

Conclusions:

1. The footplate was able to guide the blade along the meshwork successfully.
2. Liquid polyimide coating on the metal footplate insulated the tissue well.
3. Application of the liquid polyimide was relatively easy.
4. Design allows for improved and repeatable placement of the electrosurgical electrodes.



Serial N: 21-02 Jul 19 02

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GONIECTOMY DEVICE

Development History

Disease and Invention

Project Review

Regulatory Plan

Electrosurgical Goniotomy

Clinical Design

1. Demonstration of in vitro studies and feasibility
2. Ease of Manufacturing Concepts.
3. Viable insulated footplate design and implementation.

glaucoma history nov 16 01 electro.jpg

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GONIECTOMY DEVICE

Development History

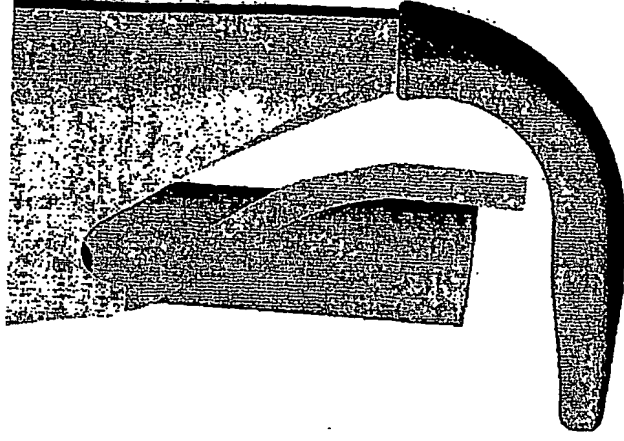
Disease and Invention

Project Review

Regulatory Plan

Electrosurgical Goniectomy *Alternative Design*

1. Two-tube design supports irrigation and aspiration.
2. Electrosurgical cutting means independent of Footplate.
3. Discharge center electrode to Return electrode.
4. Insulated guiding Footplate.



glaucoma history jul 31 02 assem electrodes x1.jpg 0.02" |

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GONIECTOMY TECHNOLOGY

Disease and Invention

Project Review

Regulatory Plan

NeoMedix Development Project

1. History of Handpiece
- 2. Current Handpiece**
3. Integrated Console System
4. Quality Plan

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GONIECTOMY TECHNOLOGY

Clinical Design Goals

Disease and Invention

Project Review

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Handpiece Features:

1. Single-use Disposable Hand-held Instrument.
2. Handpiece connects to a fluid control system consisting of I/A and an electrosurgical generator.
3. Tip designed to enter through 20G MVR blade incision.
4. Insulating material covering the tip to isolate the meshwork from thermal and electrical discharge damage.
5. The meshwork guide footplate angled at 90° relative to the handpiece.

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GONIECTOMY TECHNOLOGY

Clinical Design Goals

Disease and Invention

Project Review

Regulatory Plan

Handpiece Features: (continued)

- o The handpiece body will consist of a 2 white ABS injection molded parts.
- o Insulated electrode wire made from 316V Stainless Steel.
- o Insulation shoe material made from polyimide.
- o Full-length Irrigation / Aspiration tubing on the handpiece eliminates tubing connections.
- o Press-on electrosurgical cable connection to the handpiece rear connector.

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GONIECTOMY TECHNOLOGY

Ergonomic Considerations

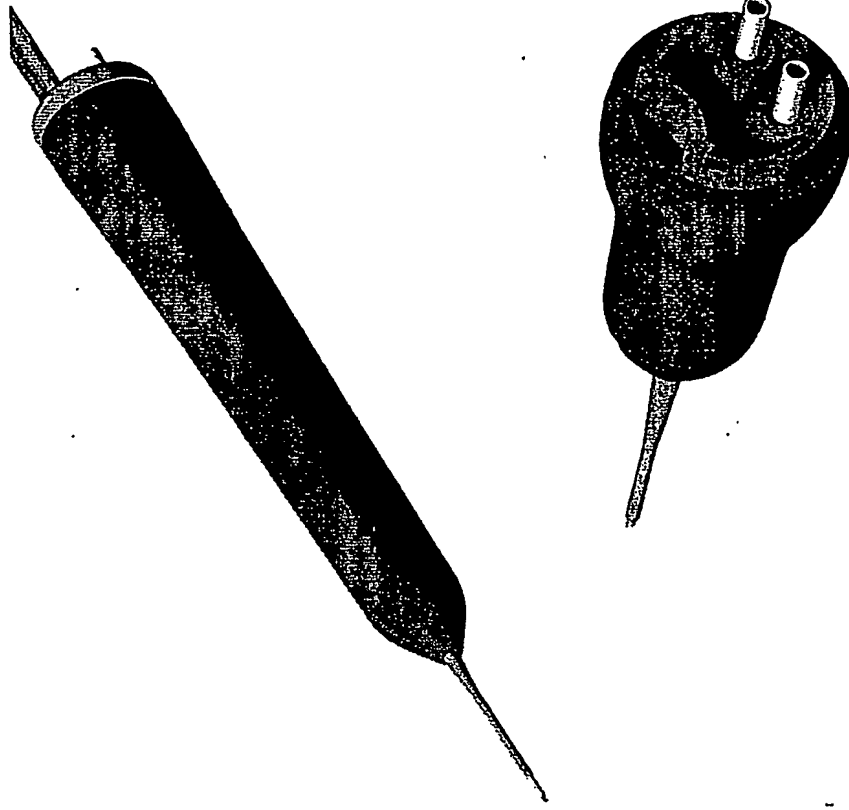
Disease and Invention

Project Review

Regulatory Plan

Ergonomic Challenges:

- o Familiar feel in Surgeon's hand.
- o Short (Vitreotomy Style) vs. Long (Pencil Style)
- o Long (Pencil Style) Approach Selected



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GONIECTOMY TECHNOLOGY

Design for Manufacturability

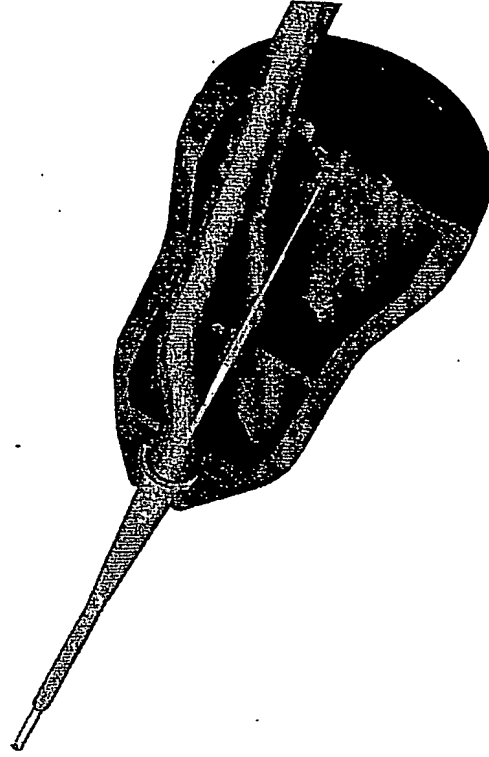
Disease and Invention

Protect Review

Regulatory Plan

Manufacturability Obstacles:

- o Clam Shell Approach Considered.
- o Routing Of Tubes And Wires Problematic.
- o Assembly Challenges Guide Design.
- o Desire To Have Greater Manufacturability.



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GONIECTOMY TECHNOLOGY

Design for Manufacturability

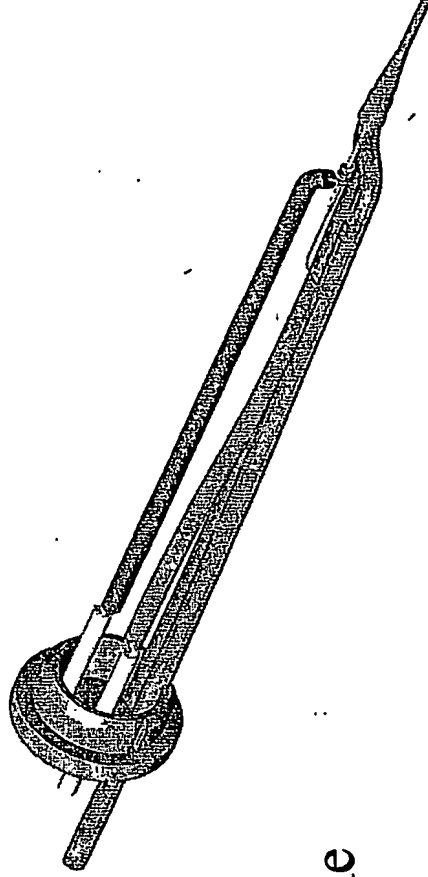
Disease and Invention

Project Review

Regulatory Plan

Manufacturability Obstacles: (continued)

- o Cap Design simple, but Cable Routing Issues Still not solved.
- o Strain Relief Issues Not Addressed.
- o Non-Rigid Assembly, Prone To Damage.
- o Yield issues after final assembly.



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GONIECTOMY TECHNOLOGY

Design Solutions

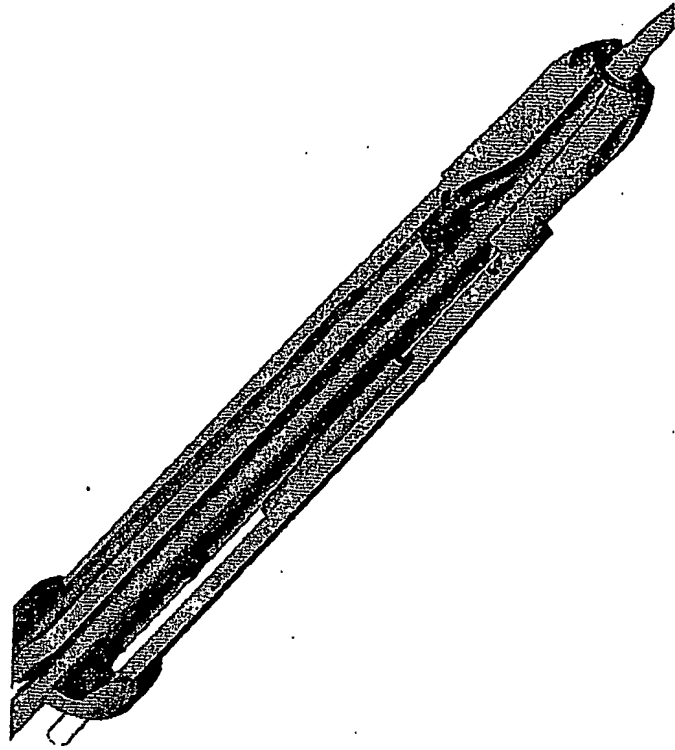
Disease and Invention

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Solutions to Manufacturability Obstacles:

- o Redesigned Rear Cap to integrate Inner Holder for all working components.
- o Strain Relief Provided for and Axial Repeatability Enhanced.
- o Tubing Paths Supported.
- o More Robust Sub-Assembly for Testing (Rigid Body).



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GONIECTOMY TECHNOLOGY

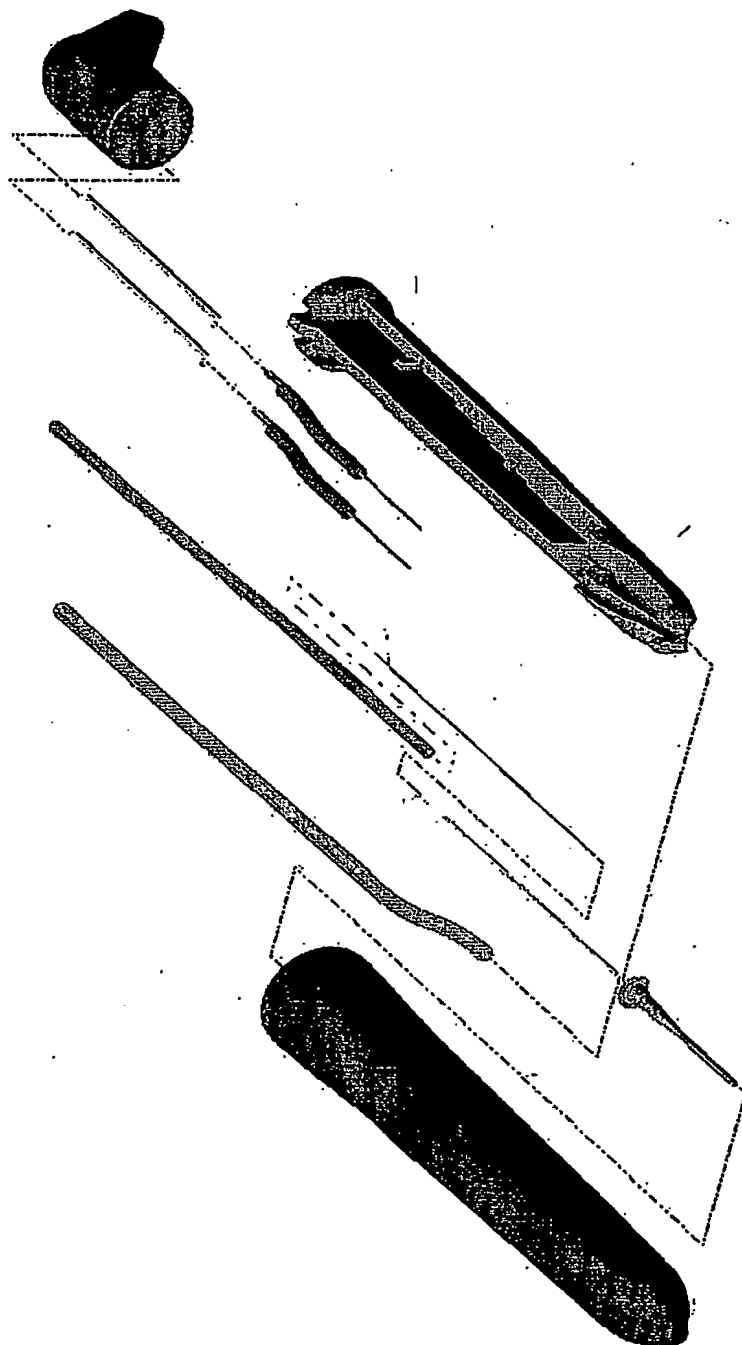
Exploded Assembly

Disease and Invention

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o Minimization of components.



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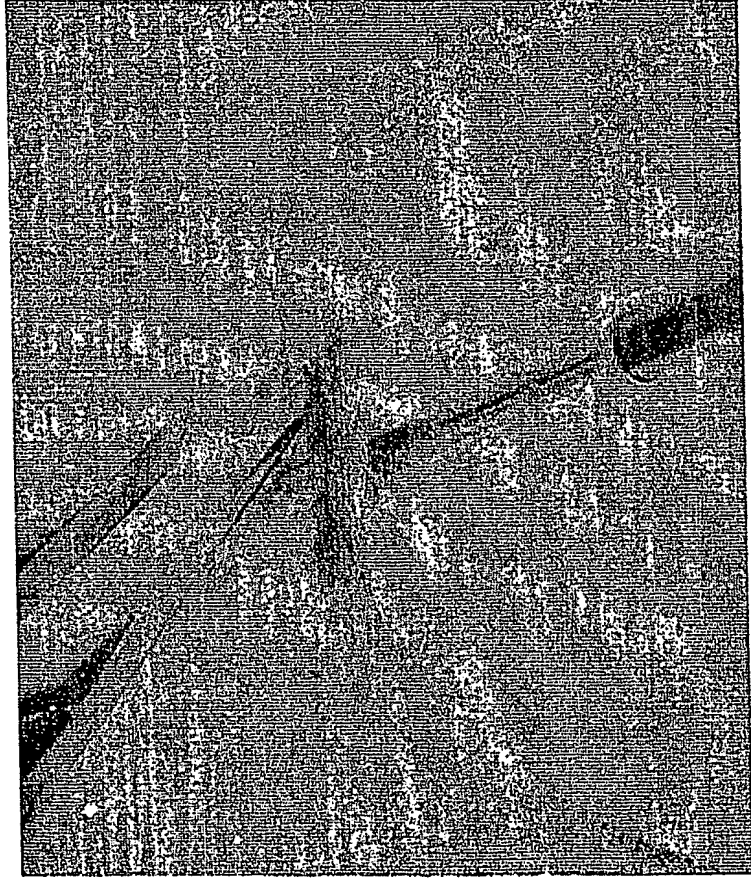
GONIECTOMY TECHNOLOGY In the Clinical Environment

Disease and Invention

Project Review

Regulatory Plan

Gonietomy Device - Clinical Version



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GONIECTOMY TECHNOLOGY Handpiece Design Goals Achieved

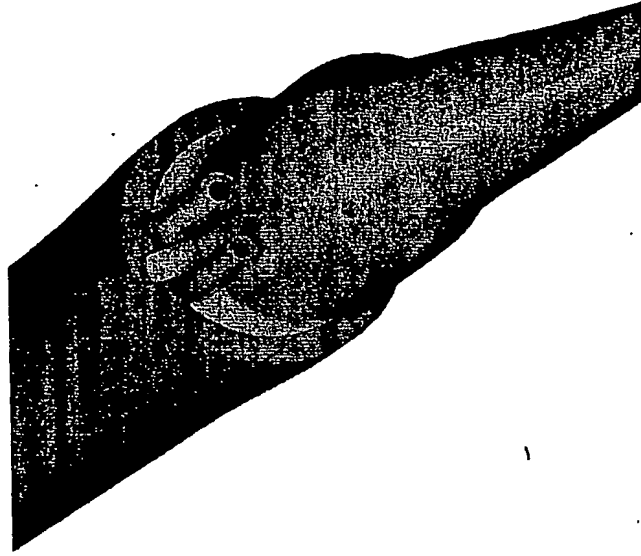
Disease and Invention

Project Review

Regulatory Plan

Design Goals Reached!

- o Push on Bi-Polar Connector fits nearly flush to Handpiece.
- o I/A Tubing are adjacent to the Connector without interference.
- o Surgeon has an ergonomic device to optimize the outcome for the patient
- o Result: Clean, Modular Handpiece Assembly.



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GONIECTOMY TECHNOLOGY

Handpiece Design: Physical Prototype

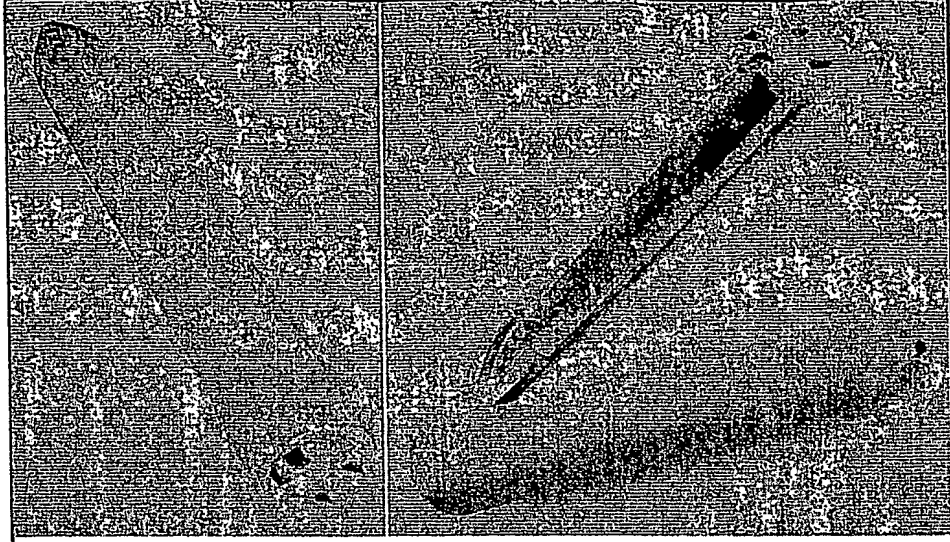
Disease and Invention

Project Review

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Handpiece Summary:

- o Met Design Challenges
- o Overcame Issues of Manufacturability.
- o Integrated Surgeon's Feedback.



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GONIECTOMY TECHNOLOGY

Disease and Invention

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1. History of Handpiece
2. Current Handpiece
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GONIECTOMY TECHNOLOGY

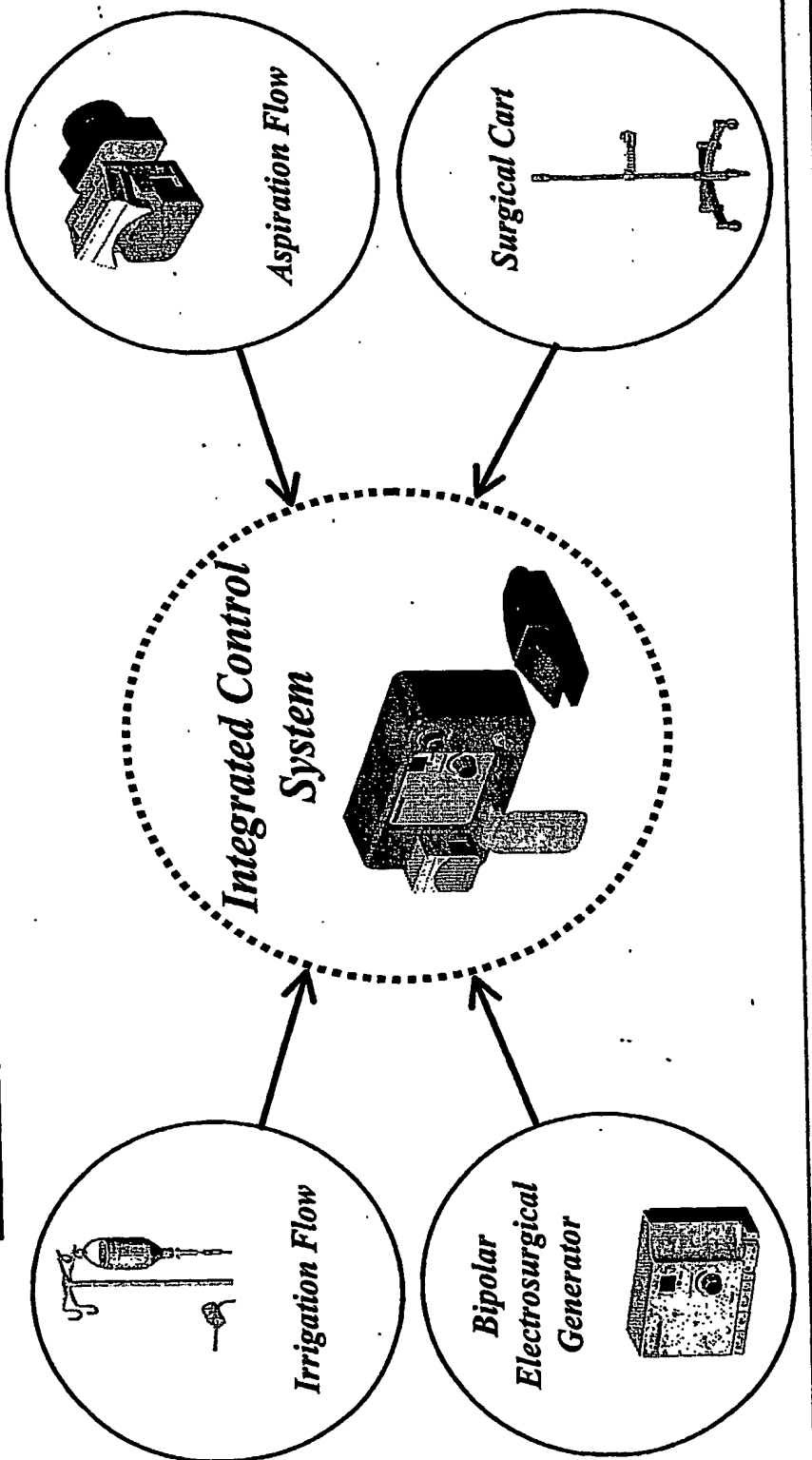
Integrated Control System

Disease and Invention

Project Review

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Console Integration Elements



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GONIECTOMY TECHNOLOGY

Integrated Control System

Disease and Invention

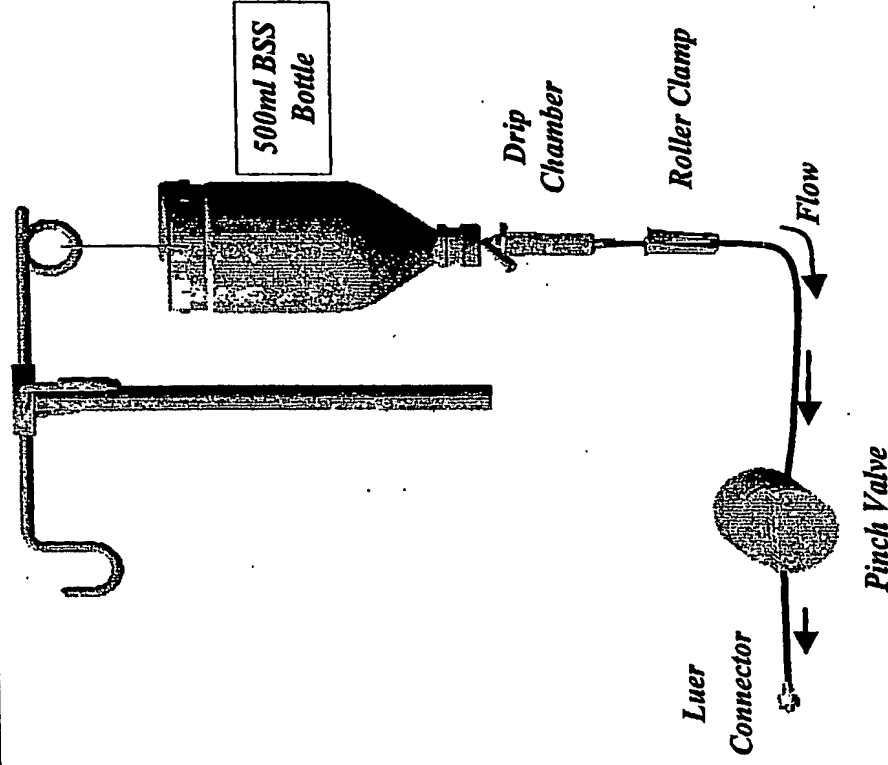
Project Review

Regulatory Plan

Console Integration:

Irrigation Sub-System

- Gravity fed irrigation of standard 500ml BSS bottle
- Adjustable bottle pole height
- Normally open pinch valve for safety
- Disconnect fitting allows for handpiece exchange



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GONNECTOMY TECHNOLOGY

Integrated Control System

Disease and Invention

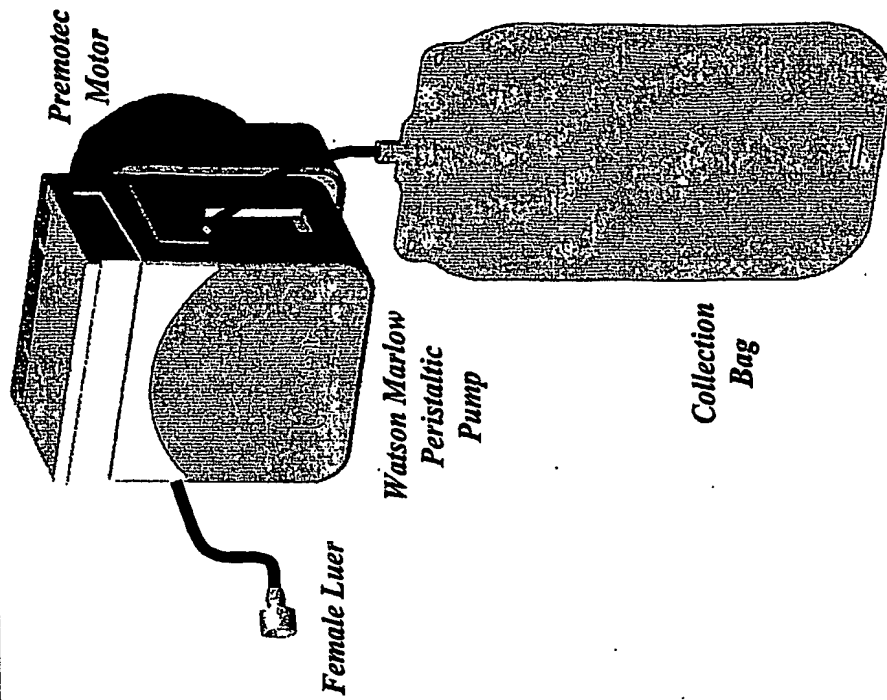
Product Review

Regulatory Plan

Console Integration:

Aspiration Sub-System

- Adjustable rate, flow-based peristaltic pump technology
- Easy tube loading/unloading
- 500ml collection bag
- No aspiration vacuum level reading or control



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Integrated Control System

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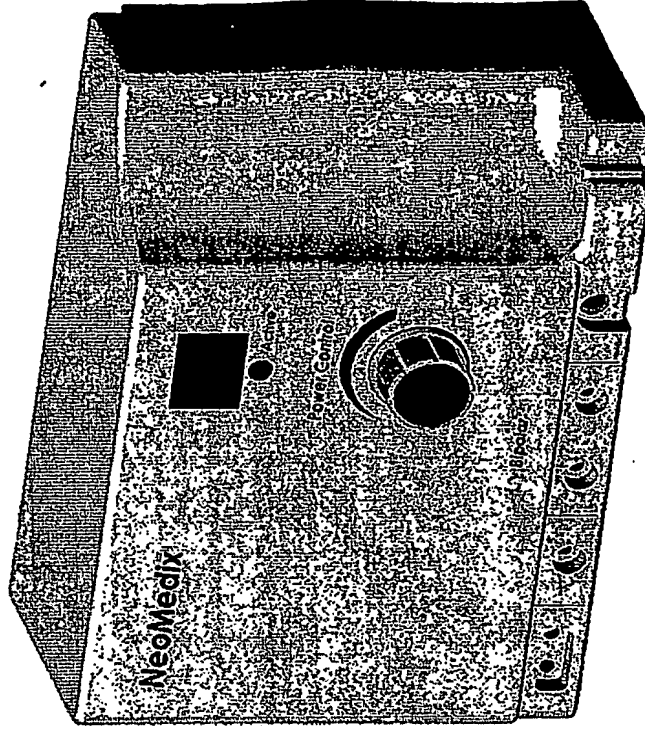
Product Review

Regulatory Plan

Console Integration Elements:

Electrosurgical Sub-System

- Full regulatory approval of Aaron 800EU
- Bipolar and monopolar capable
- Adjustable bipolar power levels from 0.1 to 30W
- Remote foot pedal control
- OEM private label customization available



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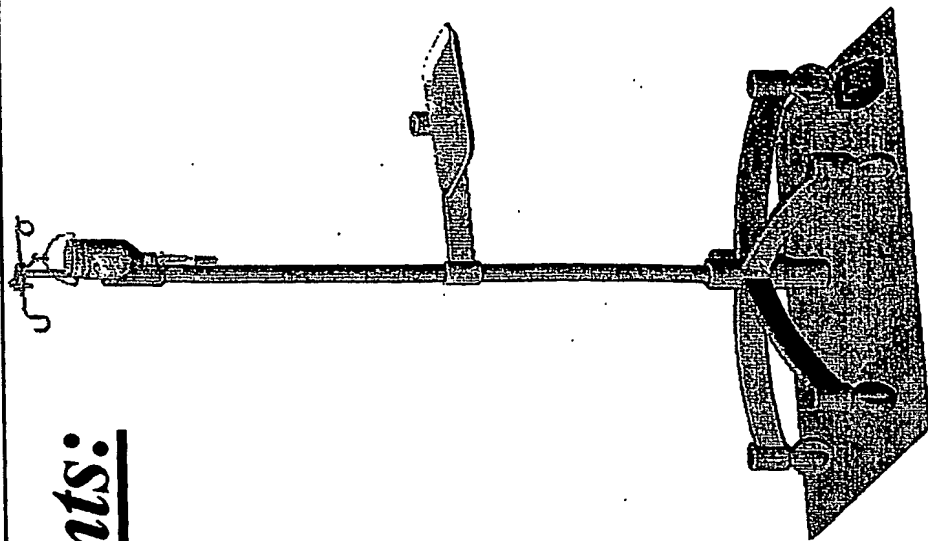
Project Review

Regulatory Plan

Console Integration Elements:

Surgical Cart

- Rolling surgical cart stands available thru GCX and Aaron Medical
- Adjustable irrigation bottle height mechanism
- Surgical tray for temporary holding of handpiece and tray packs



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Project Review

Regulatory Plan

Applicable Regulatory Standards

- FDA 510(k) (Class II)
- UL/cUL 2601
- IEC601
- IEC60601 [Medical Device Directive]
- IEC60417-1 [Graphical Symbols Standard]

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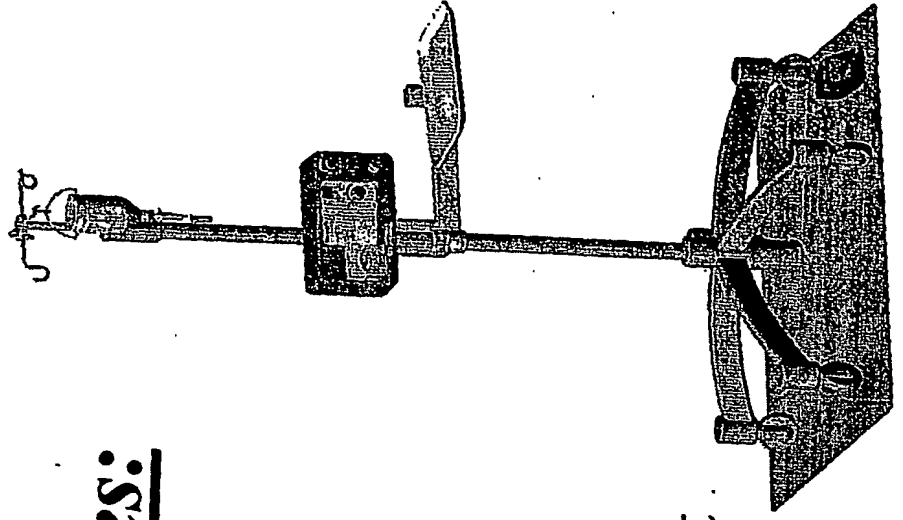
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Project Review

Regulatory Plan

Integrated Console Features:

- Fluid Flow Control Adjustment
- Irrigation Flow (On/Off)
- Aspiration Flow Rate
- Electrosurgical Power Adjustment



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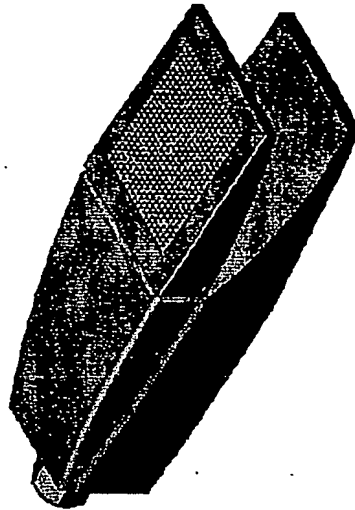
Project Review

Regulatory Plan

Footpedal Control -

3-state control system

<i>Footpedal</i>	<i>Function</i>
Region 0	All OFF
Region 1	Irrigation ON
Region 2	Add Aspiration ON
Region 3	Add Electrosurgical ON



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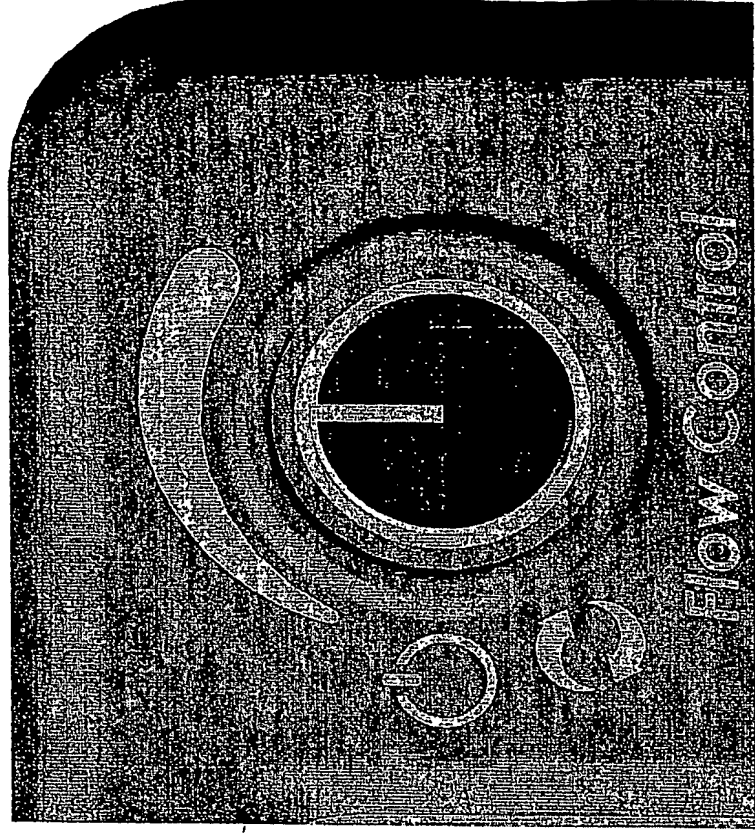
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Project Review

Regulatory Plan

3-Mode, 6-position Selector Control:

- 4 Flow Settings:
 - 2 cc/min
 - 4 cc/min
 - 6 cc/min
 - 8 cc/min
- Standby
- Purge



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Integrated Control System

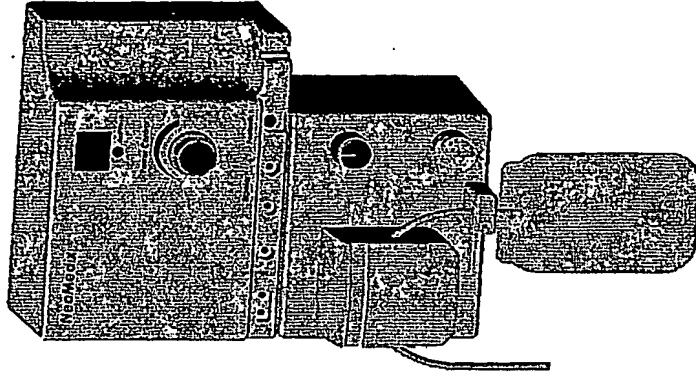
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Project Review

Regulatory Plan

Console Integration: Design History

- Original stacked configuration of I/A enclosure under Aaron 800EU
- Minimal form factor design intent
- Advantages: Small form factor and standalone I/A capable unit
- Disadvantages: Exposed cabling for footpedal bypass, exposed monopolar and return plate jacks, difficult to match styling of Aaron 800EU



Glaucoma Console June 21 2002

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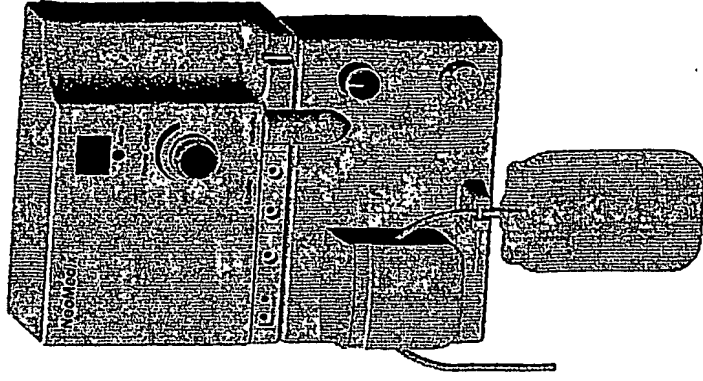
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Project Review

Regulatory Plan

Console Integration: Design History

- Intended to match the form factor and styling of Aaron 800EU
- Provided plastic extensions to cover unused jack locations of Aaron 800EU
- Advantages: Prevent misconnection of handpiece to incorrect jacks
- Disadvantages: Molding complexity, cleaning issues and mechanical instability resulting from gap between units, difficult to color/texture match



Glaucoma Console July 2 2002

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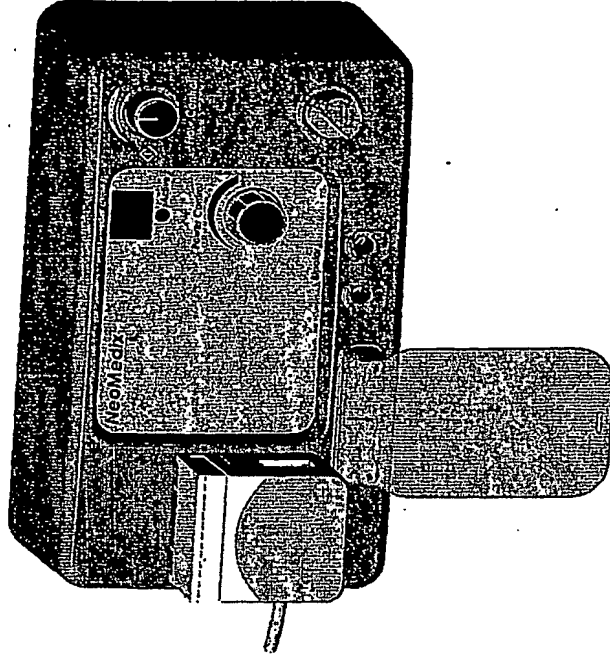
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Regulatory Plan

Console Integration: Design History

- Integrates Aaron 800EU as an enclosed, internal component
- Adds stylized features and curvature
- Advantages: Eliminates 2-part styling mismatch, leaves only usable jacks exposed, mechanically sturdy
- Disadvantages: Requires larger enclosure fabrication and transfer of covered label content on Aaron 800EU



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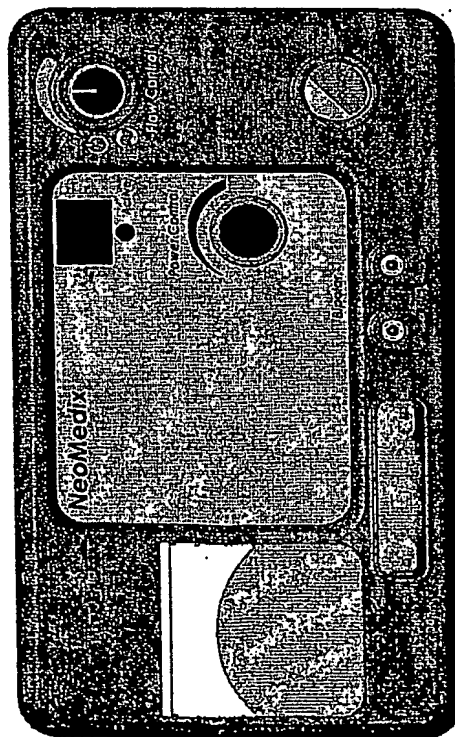
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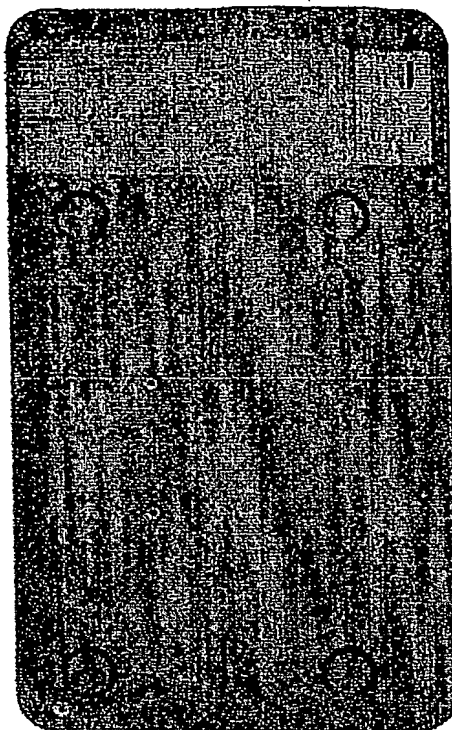
Project Review

Regulatory Plan

CONSOLE- External Design



Front Panel



Rear Panel

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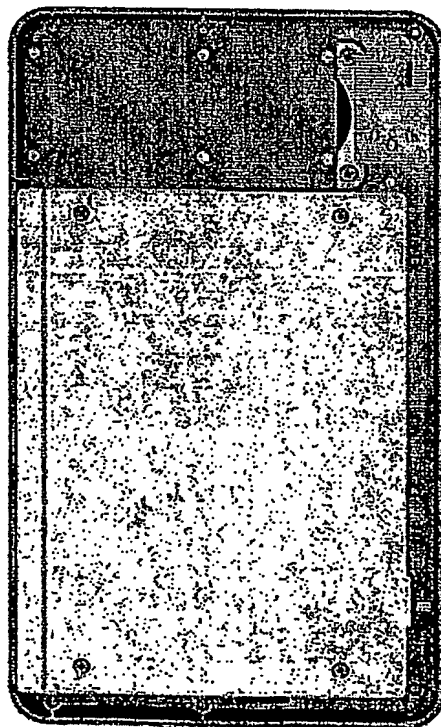
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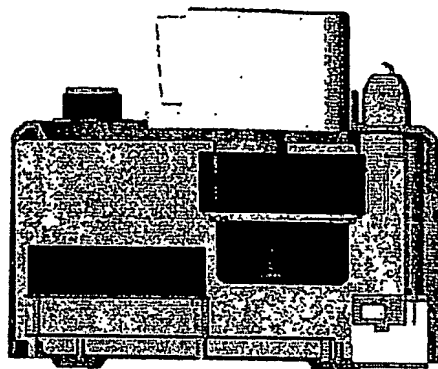
Project Review

Regulatory Plan

CONSOLE- Internal Design



Rear Panel



Side Panel

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Project Review

Regulatory Plan

Production

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GONIECTOMY TECHNOLOGY

Design and Production Capabilities

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CONSOLE- Manufacturing

- Stereolithography rapid prototyping
- CNC Machining
- Advanced manufacturing, assembly, and test equipment capabilities



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GONIECTOMY TECHNOLOGY

Manufacturing for Production

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Project Review

Regulatory Plan

Handpiece- Manufacturing

- FDA Registered Facility
- Certified Class 10,000 Controlled Environment
- Extensive Micro-assembly and Inspection Equipment



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GONIECTOMY TECHNOLOGY

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Project Review

Regulatory Plan

NeoMedix Development Project

1. History of Handpiece
2. Current Handpiece
3. Integrated Console System
4. Quality Plan

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GONIECTOMY TECHNOLOGY

Quality Plan

Disease and Invention

Project Review

Regulatory Plan

NeoMedix Development Project

Production Development Phases:

1. Prototype
2. Clinical
3. Pre-Production
4. Production

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GONIECTOMY TECHNOLOGY

Quality Plan

Disease and Invention

Project Review

Regulatory Plan

NeoMedix Development Project

Prototype Phase:

- | | |
|---------------------------------------|---|
| 1. User Requirement Specification | 8. Clinical Investigation (If applicable) |
| 2. Product Specification (Functional) | 9. Draft of Labeling |
| 3. Initial FMEA (EN 1441) | 10. Documentation |
| 4. In Vitro Testing | 11. Design review |
| 5. In Vivo Testing | 12. Process Requirement Defined |
| 6. Biocompatibility Method | 13. Special and Key Processes Identified |
| 7. Sterilization Method | 14. Receiving Inspection |

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Quality Plan

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NeoMedix Development Project

Clinical Phase:

- | | |
|------------------------------------|-----------------------------------|
| 1. Validation Test Report | 8. Labeling Completed |
| 2. Completed FMEA | 9. Environmental Controls |
| 3. Equipment Validation | 10. Vendor Qualification |
| 4. Process Control in Place | 11. Manufacturing Instruction |
| 5. Biocompatibility Completed | 12. Process Instruction |
| 6. Sterilization Validation Report | 13. Drawings Release |
| 7. Design Review | 14. Bill of Materials Release |
| | 15. In-process, Final Instruction |
| | 16. Device History Record |

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GONIECTOMY TECHNOLOGY

Quality Plan

Disease and Invention

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NeoMedix Development Project

Pre-Production:

1. FDA Clearance
2. Foreign Approvals (CE)
3. Design Review
4. Document Release
5. Device Master Record
6. Corrective Action System

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GONIECTOMY TECHNOLOGY

Quality Plan

Disease and Invention

Project Review

Regulatory Plan

NeoMedix Development Project

Production:

1. Failure Analysis Performed
2. Corrective Action System
3. Internal Audits Performed
4. Design Review
5. Documents Release

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Regulatory Plan

NeoMedix Development Project

1. History of Handpiece
2. Current Handpiece
3. Integrated Console System
4. Quality Plan

Done

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GONNECTOMY PROJECT

Disease and Invention

Project Review

Regulatory Plan

Overview

Disease and Invention

Project Review

Regulatory Plan

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